REFERENCE

CANADA

1954

OFFICE CONSOLIDATION

OF THE

FOOD AND DRUGS ACT

AND OF THE

FOOD AND DRUG REGULATIONS

TLMS

ISSUED BY

DEPARTMENT OF NATIONAL HEALTH AND WELFARE

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FOREWORD

This edition of the office consolidation of the Food and Drugs Act and the Food and Drug Regulations presents a complete revision of the Act and the regulations made in 1953 and 1954 respectively.

The revision of the Food and Drugs Act (R.S., 1927, c.76 as amended) was undertaken to remove some apparent contradictions and anomalies and to deal with the various articles under its authority separately and more specifically. Additional powers were given in the revised Act where they were necessary to carry out its intent, which is to protect the public against health hazards and fraud in the sale and use of foods, drugs, cosmetics and medical devices.

The result has been that the subject matter is dealth with in a more orderly and logical way and certain inconsistencies have been removed. The new authority and requirements of the Food and Drugs Act include the following:—

(i) the maintenance of such books and records as may be deemed necessary by the Governor in Council for the proper administration and enforcement of the Act and regulations,

(ii) the right of inspectors to examine and copy such records for the purpose of administration and enforcement,

(iii) a prohibition of the sale of foods, drugs or cosmetics manufactured under unsanitary conditions and a prohibition of the manufacture, preparation, preservation, packaging and storage of foods, drugs or cosmetics under unsanitary conditions,

(iv) in cases of dispute, a means for judicial decision as to whether seizures shall be forfeited to the Crown for disposal according to the Minister's direction,

(v) enforcement changes such as increased penalties, abolition of voluntary settlements for infractions of the law, and provision for trial by indictment as well as by summary conviction.

Some editorial changes may be observed. An attempt has been made to eliminate constant and monotonous repetition of phrases such as "legibly and conspicuously". Instead of the repetition, one regulation makes it clear that this is a requirement throughout. Other examples may be found and it is recommended that persons concerned with the regulations should carefully read Part A which applies to all other parts. In addition they should in every instance be guided by the general section of each part.

As far as possible, if a regulation governing a specific commodity or condition is contrary to or modified by another regulation, the specific regulation dealing with the change is indicated by a reference to the section number. Where the terms "subject to" followed by a reference, "subject to these regulations", "except as provided by" followed by a reference, or "except as provided in these regulations" occur, they invariably indicate that the precise terms of the regulation in which they occur are modified by another regulation or regulations. Such modified conditions should be carefully examined and followed where applicable. The term "notwithstanding" followed by a reference has the effect of nullifying the provisions of the specific reference given and of substituting therefor the provisions of the regulation in which it occurs.

An office consolidation is a document of convenience and may be relied on for information. It is intended to afford easier reading by including explanatory notes, indexes, and other material of an ancillary nature. The letter of the law, however is to be found in the Statutes, and in the regulations as they are published in the *Canada Gazette*. The instruments establishing the present form of the Act are listed on page vi and those establishing the regulations on page 12.

Each section of the regulations is so identified by letter and number that there can be no duplication of identifying mark and so that the mark itself clearly designates the position of each section in relation to all other sections. This is done by using a six character mark consisting in order of a single letter, a two figure number, and a three figure number, separated by periods. The single letter refers to one of the PARTS into which the whole regulations are first divided, for instance PART C which refers only to DRUGS or PART B which refers only to FOODS; the two figure numbers following the letter denote subject DIVISIONS into which the PARTS are subdivided, for instance B.03 means DIVISION 3 of PART B and its subject is Baking Powder; each DIVISION is further broken down into the actual SECTIONS of the regulations. The zeros in the identifying marks are significant and may not be omitted. To speak or write about any SECTION it is only necessary to quote the number.

Although an Index is provided, the TABLE of CONTENTS may often be used instead. In general the user of this office consolidation can find all he needs to know about a commodity by reading the SECTIONS devoted to it and by reading the GENERAL DIVISION (the first division) in the particular PART in which the item appears; where there are exceptions or additions to the GENERAL requirements footnotes are usually provided.

Labelling requirements have been, as far as possible, grouped together in each PART, usually in DIVISION 1 thereof, but if there are special labelling requirements for a commodity, over and above the general ones, they will be found in the SECTIONS relating to that commodity.

Since labelling requirements demand the common or proper name of an article or ingredient to be used it has been provided that where applicable, and unless otherwise taken care of, the names of foods or drugs printed in **bold-face type** are the names to be used as common or proper names.

Where the regulations require statements to be given on labels, if the statements are printed in the regulations between quotation marks they must be reproduced exactly as they are given in the regulations.

The "usual dosages" appearing in DIVISION 6 of PART C are not part of the regulations and are merely to be recognized as a convenient guide.

Chapter 38 of the Statutes of Canada, 1953.

Schedule A to the Act.

Schedule B to the Act as amended by P.C. 1954-943 of 24th June, 1954, P.C. 1954-1729 of 18th November, 1954, and P.C. 1956-545 of 5th April, 1956.

Schedule C to the Act.

Schedule D to the Act.

Schedule E to the Act.

Schedule F to the Act as amended by P.C. 1954-943 of 24th June, 1954,
by P.C. 1954-1671 of 3rd November, 1954,
by P.C. 1954-1731 of 18th November, 1954,
by P.C. 1955-327 of 8th March, 1955,
by P.C. 1956-546 of 5th April, 1956, and
by P.C. 1956-1053 of 12th July, 1956.

AN ACT RESPECTING FOOD AND DRUGS

Short Title.

1. This Act may be cited as the *Food and Drugs Act*. Short title.

Interpretation.

2. In this Act, Definitions.

(a) "advertisement" includes any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device; "advertisement".

(b) "analyst" means any person designated as a Food and Drug Analyst under subsection (2) of section 24; "analyst".

(c) "cosmetic" includes any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth, and includes deodorants and perfumes; "cosmetic".

(d) "department" means the Department of National Health and Welfare; "department"

(e) "device" means any instrument, apparatus or contrivance, including components, parts, and accessories thereof, manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof, in man or animal; "device".

(f) "drug" includes any substance or mixture of substances manufactured, sold or represented for use in "drug".

(i) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof, in man or animal,

(ii) restoring, correcting or modifying organic functions in man or animal, or

(iii) disinfection in premises in which food is manufactured, prepared or kept, or for the control of vermin in such premises;

(g) "food" includes any article manufactured, sold or represented for use as food or drink for man, chewing gum, and any ingredient that may be mixed with food for any purpose whatever; "food".

(h) "inspector" means any person designated as a Food and Drug Inspector under subsection (2) of section 24; "inspector".

(i) "label" includes any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package; "label".

(j) "Minister" means the Minister of National Health and Welfare; "Minister".

(k) "package" includes anything in which any food, drug, cosmetic or device is wholly or partly contained, placed or packed; "package".

(l) "prescribed" means prescribed by the regulations; "prescribed".

(m) "sell" includes sell, offer for sale, expose for sale, have in possession for sale, and distribute; and "sell".

(n) "unsanitary conditions" means such conditions or circumstances as might contaminate a food, drug or cosmetic with dirt or filth or render the same injurious to health. "unsanitary conditions".

PART I.

Foods, Drugs, Cosmetics and Devices

General.

No food, drug, etc., to be advertised or sold as a treatment, etc., for certain diseases.

3. (1) No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states mentioned in Schedule A.

Idem.

(2) No person shall sell any food, drug, cosmetic or device

(a) that is represented by label, or

(b) that he advertises to the general public

as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states mentioned in Schedule A.

Food.

Prohibited sales of food.

4. No person shall sell an article of food that

(a) has in or upon it any poisonous or harmful substance;

(b) is unfit for human consumption;

(c) consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance;

(d) is adulterated; or

(e) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.

Deception.

5. (1) No person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

Idem.

(2) An article of food that is not labelled or packaged as required by the regulations, or is labelled or packaged contrary to the regulations, shall be deemed to be labelled or packaged contrary to subsection (1).

Where standard prescribed.

6. Where a standard has been prescribed for a food, no person shall label, package, sell or advertise any article in such a manner that it is likely to be mistaken for such food, unless the article complies with the prescribed standard.

Manufacture of food under unsanitary conditions.

7. No person shall manufacture, prepare, preserve, package or store for sale any food under unsanitary conditions.

Drugs.

Prohibited sales of drugs.

8. No person shall sell any drug that

(a) was manufactured, prepared, preserved, packed or stored under unsanitary conditions; or

(b) is adulterated.

Deception.

9. (1) No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

Idem.

(2) A drug that is not labelled or packaged as required by the regulations, or is labelled or packaged contrary to the regulations, shall be deemed to be labelled or packaged contrary to subsection (1).

10. (1) Where a standard has been prescribed for a drug, no person shall label, package, sell or advertise any substance in such a manner that it is likely to be mistaken for such drug, unless the substance complies with the prescribed standard. Where standard prescribed.

(2) Where a standard has not been prescribed for a drug, but a standard for the drug is contained in any publication mentioned in Schedule B, no person shall label, package, sell or advertise any substance in such a manner that it is likely to be mistaken for such drug, unless the substance complies with such standard. Trade standards.

(3) Where a standard for a drug has not been prescribed and no standard for the drug is contained in any publication mentioned in Schedule B, no person shall sell such drug, unless Professed standards.

(a) it is in accordance with the professed standard under which it is sold, and

(b) it does not resemble, in a manner likely to deceive, any drug for which a standard has been prescribed or is contained in any publication mentioned in Schedule B.

11. No person shall manufacture, prepare, preserve, package or store for sale any drug under unsanitary conditions. Manufacture of drug under unsanitary conditions.

12. No person shall sell any drug described in Schedule C or D unless the Minister has, in prescribed form and manner, indicated that the premises in which the drug was manufactured and the process and conditions of manufacture therein are suitable to ensure that the drug will not be unsafe for use. Sale of certain drugs prohibited unless safe conditions.

13. No person shall sell any drug described in Schedule E unless the Minister has, in prescribed form and manner, indicated that the batch from which the drug was taken is not unsafe for use. Idem.

14. (1) No person shall distribute or cause to be distributed any drug as a sample. Distribution of samples prohibited.

(2) Subsection (1) does not apply to the distribution of samples of drugs by mail or otherwise to physicians, dentists or veterinary surgeons or to the distribution of drugs, other than those mentioned in Schedule F, to registered pharmacists for individual redistribution to adults only or to a distributor in compliance with individual requests. Exception.

Cosmetics.

15. No person shall sell any cosmetic that Prohibited sales of cosmetics.

(a) has in or upon it any substance that may cause injury to the health of the user when the cosmetic is used,

(i) according to the directions on the label or accompanying such cosmetic, or

(ii) for such purposes and by such methods of use as are customary or usual therefor;

(b) consists in whole or in part of any filthy or decomposed substance or of any foreign matter; or

(c) was manufactured, prepared, preserved, packed or stored under unsanitary conditions.

16. Where a standard has been prescribed for a cosmetic, no person shall label, package, sell or advertise any article in such a manner that it is likely to be mistaken for such cosmetic, unless the article complies with the prescribed standard. Where standard prescribed.

Manufacture under unsanitary conditions.

17. No person shall manufacture, prepare, preserve, package or store for sale any cosmetic under unsanitary conditions.

Devices.

Prohibited sales of devices.

18. No person shall sell any device that, when used according to directions or under such conditions as are customary or usual, may cause injury to the health of the purchaser or user thereof.

Deception.

19. (1) No person shall label, package, treat, process, sell or advertise any device in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, composition, merit or safety.

Idem.

(2) A device that is not labelled or packaged as required by the regulations, or is labelled or packaged contrary to the regulations, shall be deemed to be labelled or packaged contrary to subsection (1).

Where standard prescribed.

20. Where a standard has been prescribed for a device, no person shall label, package, sell or advertise any article in such a manner that it is likely to be mistaken for such device, unless the article complies with the prescribed standard.

PART II.

Administration and Enforcement

Powers of Inspectors.

Powers of inspectors.

21. (1) An inspector may at any reasonable time

(a) enter any place where on reasonable grounds he believes any article to which this Act or the regulations apply is manufactured, prepared, preserved, packaged or stored, examine any such article and take samples thereof, and examine anything that he reasonably believes is used or capable of being used for such manufacture, preparation, preservation, packaging or storing;

(b) open and examine any receptacle or package that on reasonable grounds he believes contains any article to which this Act or the regulations apply;

(c) examine any books, documents or other records found in any place mentioned in paragraph *(a)* that on reasonable grounds he believes contain any information relevant to the enforcement of this Act with respect to any article to which this Act or the regulations apply and make copies thereof or extracts therefrom; and

(d) seize and detain for such time as may be necessary any article by means of or in relation to which he reasonably believes any provision of this Act or the regulations have been violated.

Definition.

(2) For the purposes of subsection (1), the expression "article to which this Act or the regulations apply" includes

(a) any food, drug, cosmetic or device,

(b) anything used for the manufacture, preparation, preservation, packaging or storing thereof, and

(c) any labelling or advertising material.

Inspector to show certificate of appointment.

(3) An inspector shall be furnished with a prescribed certificate of designation and on entering any place pursuant to subsection (1) shall if so required produce the certificate to the person in charge thereof.

(4) The owner or person in charge of a place entered by an inspector pursuant to subsection (1) and every person found therein shall give the inspector all reasonable assistance in his power and furnish him with such information as he may reasonably require. Owner to give assistance to inspector.

(5) No person shall obstruct an inspector in the carrying out of his duties under this Act or the regulations. Obstructing inspector.

(6) No person shall knowingly make any false or misleading statement either verbally or in writing to any inspector engaged in carrying out his duties under this Act or the regulations. False statements.

(7) No person shall remove, alter or interfere in any way with any article seized under this Act without the authority of an inspector. Interferences with articles seized.

(8) Any article seized under this Act may at the option of an inspector be kept or stored in the building or place where it was seized or may at the direction of an inspector be removed to any other proper place. Storing of seized articles.

Forfeiture.

22. (1) An inspector shall release any article seized by him under this Act when he is satisfied that all the provisions of this Act and the regulations with respect thereto have been complied with. Release of seized articles.

(2) Where an inspector has seized an article under this Act and the owner thereof or the person in whose possession the article was at the time of seizure consents to the destruction thereof, the article is thereupon forfeited to Her Majesty and may be destroyed or otherwise disposed of as the Minister may direct. Destruction with consent.

(3) Where a person has been convicted of a violation of this Act or the regulations, the court or judge may order that any article by means of or in relation to which the offence was committed or anything of a similar nature belonging to or in the possession of the accused or found with such article, be forfeited, and upon such order being made, such articles and things are forfeited to Her Majesty and may be disposed of as the Minister may direct. Forfeiture upon conviction.

(4) Without prejudice to the operation of subsection (3), a judge of a superior, county or district court of the province in which any article was seized under this Act may, on the application of an inspector and on such notice to such persons as the judge directs, order that the article and anything of a similar nature found therewith be forfeited to Her Majesty to be disposed of as the Minister may direct, if the judge finds, after making such inquiry as he considers necessary, that the article is one by means of or in relation to which any of the provisions of this Act or the regulations were violated. Order for forfeiture.

Analysis.

23. (1) An inspector may submit any article seized by him or any sample therefrom or any sample taken by him to an analyst for analysis or examination. Analysis.

(2) Where an analyst has made an analysis or examination he may issue a certificate or report setting forth the results of his examination or analysis. Report.

Regulations.

24. (1) The Governor in Council may make regulations for carrying the purposes and provisions of this Act into effect, and, in particular, but not so as to restrict the generality of the foregoing, may make regulations Regulations.

(a) declaring that any food or drug or class of food or drugs is adulterated if any prescribed substance or class of substances is present therein or has been added thereto or extracted or omitted therefrom;

(b) respecting

(i) the labelling and packaging and the offering, exposing and advertising for sale of food, drugs, cosmetics and devices,

(ii) the size, dimensions, fill and other specifications of packages of food, drugs, cosmetics and devices,

(iii) the sale or the condition of sale of any food, drug, cosmetic or device, and

(iv) the use of any substance as an ingredient in any food, drug, cosmetic or device,

to prevent the consumer or purchaser thereof from being deceived or misled as to its quantity, character, value, composition, merit or safety or to prevent injury to the health of the consumer or purchaser;

(c) prescribing standards of composition, strength, potency, purity, quality or other property of any article of food, drug, cosmetic or device;

(d) respecting the importation of foods, drugs, cosmetics and devices in order to ensure compliance with this Act and the regulations;

(e) respecting the method of preparation, manufacture, preserving, packing, storing and testing of any food, drug, cosmetic or device in the interest of, or for the prevention of injury to, the health of the consumer or purchaser;

(f) requiring persons who sell food, drugs, cosmetics or devices to maintain such books and records as the Governor in Council considers necessary for the proper enforcement and administration of this Act and the regulations;

(g) respecting the form and manner of the Minister's indication under section 12, including the fees payable therefor, and prescribing what premises or what processes or conditions of manufacture, including qualifications of technical staff, shall or shall not be deemed to be suitable for the purposes of that section;

(h) requiring manufacturers of any drugs described in Schedule E to submit test portions of any batch of such drugs and respecting the form and manner of the Minister's indication under section 13, including the fees payable therefor;

(i) not inconsistent with this Act, respecting the powers and duties of inspectors and analysts and the taking of samples and the seizure, detention, forfeiture and disposition of articles;

(j) exempting any food, drug, cosmetic or device from all or any of the provisions of this Act and prescribing the conditions of such exemption;

(k) prescribing forms for the purposes of this Act and the regulations;

(l) providing for the analysis of food, drugs or cosmetics other than for the purposes of this Act and prescribing a tariff of fees to be paid for such analysis; and

(m) adding anything to any of the Schedules, in the interest of, or for the prevention of injury to, the health of the consumer or purchaser, or deleting anything therefrom.

Analysts and inspectors.

(2) The Governor in Council may designate as an analyst or inspector any person on the staff of the department for such time as that person is employed in the department or for such time during the period of such employment as he may direct.

Penalties.

Penalties.

25. Every person who violates any of the provisions of this Act or the regulations is guilty of an offence and is liable

(a) on summary conviction for a first offence to a fine not exceeding five hundred dollars or to imprisonment for a term not exceeding three months or to both fine and imprisonment, and for a subsequent offence to a fine not exceeding one thousand dollars or to imprisonment for a term not exceeding six months or to both fine and imprisonment; and

(b) on conviction upon indictment to a fine not exceeding five thousand dollars or to imprisonment for a term not exceeding three years or to both fine and imprisonment.

Time-limit.

26. A prosecution under paragraph *(a)* of section 25 may be instituted at any time within twelve months from the time the subject-matter of the prosecution arose.

Venue.

27. A prosecution for a violation of this Act or the regulations may be instituted, heard, tried or determined in the place in which the offence was committed or the subject-matter of the prosecution arose or in any place in which the accused is apprehended or happens to be.

Want of knowledge.

28. (1) Subject to subsection (2), in a prosecution for the sale of any article in contravention of this Act or the regulations, if the accused proves to the satisfaction of the court or judge that

(a) he purchased the article from another person in packaged form and sold it in the same package and in the same condition the article was in at the time he purchased it, and

(b) that he could not with reasonable diligence have ascertained that the sale of the article would be in contravention of this Act or the regulations,

the accused shall be acquitted.

Notice.

(2) Subsection (1) does not apply in any prosecution unless the accused, at least ten days before the day fixed for the trial, has given to the prosecutor notice in writing that he intends to avail himself of the provisions of subsection (1) and has disclosed to the prosecutor the name and address of the person from whom he purchased the article and the date of purchase.

Evidence.

Certificates of analysis.

29. (1) A certificate of an analyst stating that he has analyzed or examined an article or a sample submitted to him by an inspector and stating the result of his examination is admissible in evidence in a prosecution for a violation of this Act or the regulations, and is *prima facie* proof of the statements contained in the certificate the party against whom it is produced may require the attendance of the analyst for the purpose of cross-examination; but no such certificate shall be received in evidence unless the party intending to produce it has, before the trial, given to the party against whom it is intended to be produced, reasonable notice of such intention together with a copy of the certificate.

Name of manufacturer.

(2) Proof that a package containing any article to which this Act or the regulations apply bore a name or address purporting to be the name or address of the person by whom it was manufactured or packaged is *prima facie* proof, in a prosecution for a violation of this Act or the regulations, that the article was manufactured or packaged, as the case may be, by the person whose name or address appeared on the package.

Offence by employees.

(3) In a prosecution for a violation of this Act or the regulations it is sufficient proof of the offence to establish that it was committed by an employee or agent of the accused whether or not he is identified or has been prosecuted for the offence.

Copies of records.

(4) In a prosecution for a violation of this Act or the regulations a copy of a record or an extract therefrom certified to be a true copy by the inspector who made it pursuant to paragraph *(c)* of subsection (1) of section 21 is receivable in evidence and is *prima facie* proof of the contents thereof.

Possession of adulterating substances.

(5) Where a person is prosecuted under this Act for having manufactured an adulterated food or drug for sale, and it is established that

(a) the food or drug has by regulation been declared to be adulterated if any prescribed substance has been added thereto, and

(b) such person had in his possession or on his premises any such prescribed substance,

the onus of proving that the food or drug was not adulterated by the addition of such substance lies on the accused.

Exports.

Exports.

30. This Act does not apply to any packaged food, drug, cosmetic or device, not manufactured for consumption in Canada and not sold for consumption in Canada, if the package is marked in distinct overprinting with the word "Export", and a certificate that the package and its contents do not contravene any known requirement of the law of the country to which it is or is about to be consigned, has been issued in respect thereof in prescribed form and manner.

Coming into Force and Repeal.

Coming into force.

31. (1) This Act shall come into force on a day to be fixed by proclamation of the Governor in Council.

Repeal.

(2) If this Act comes into force before the day on which the Revised Statutes of Canada, 1952, come into force, then the *Food and Drugs Act,* chapter 76 of the Revised Statutes of Canada, 1927, is repealed on the day this Act comes into force and the *Food and Drugs Act,* chapter 123 of the Revised Statutes of Canada, 1952, is repealed on the day the Revised Statutes of Canada, 1952, come into force.

Idem.

(3) If this Act comes into force on or after the day on which the Revised Statutes of Canada, 1952, come into force, then the *Food and Drugs Act,* chapter 123 of the Revised Statutes of Canada, 1952, is repealed on the day this Act comes into force.

SCHEDULE A.

Alcoholism
Appendicitis
Arteriosclerosis
Blood Poisoning
Bright's Disease
Cancer
Diabetes
Diphtheria
Disorders of menstrual flow
Disorders of the prostatic gland
Dropsy
Epilepsy
Erysipelas
Gallstones, Kidney Stones, Bladder Stones
Gangrene
Goitre
Heart Diseases
High Blood Pressure
Infantile Paralysis
Influenza
Lockjaw
Locomotor Ataxia
Obesity
Pleurisy
Pneumonia
Ruptures
Scarlet Fever
Sexual Impotence
Small Pox
Spinal Meningitis
Trachoma
Tuberculosis
Tumours
Typhoid Fever
Ulcers of the gastro-intestinal tract
Venereal Diseases

SCHEDULE B

Name	Abbreviation	Edition
Pharmacopoea Internationalis	(Ph. I)	I
The British Pharmacopoeia	(B.P.)	1953
The Pharmacopoeia of the United States of America	(U.S.P.)	XV
Codex Français	(Codex)	VII
The Canadian Formulary	(C.F.)	1949
The British Pharmaceutical Codex	(B.P.C.)	1954
The National Formulary	(N.F.)	X

SCHEDULE C.

Liver extract injectable
Liver extract injectable with other medication
Liver extract injectable crude
Liver extract injectable crude with other medication
Insulin
Insulin made from zinc-insulin crystals
Protamine zinc insulin
Globin insulin with zinc
NPH Insulin
Anterior pituitary extracts
Radioactive isotopes

SCHEDULE D.

Living vaccines for oral or parenteral use
Drugs prepared from micro-organisms or viruses for parenteral use
Sera and drugs analogous thereto for parenteral use
Antibiotics for parenteral use

SCHEDULE E.

Arsphenamine
Dichlorophenarsine Hydrochloride
Neoarsphenamine
Oxophenarsine Hydrochloride
Sulpharsphenamine

SCHEDULE F.

Part I

Amphetamine and any salt thereof
Barbituric acid and any salt, homologue, or derivative thereof
Bromal and the following derivatives:
    bromal hydrate, brometone, bromoform
Carbromal and the following derivatives:
    acetylcarbromal, bromisoval
    diethylbromacetamide, allylisopropylacetylurea
Chloral and the following derivatives:
    chloral hydrate (except in preparations for external use containing not more than 1 per cent), alpha-chloralose, chloralformamide, butyl chloral hydrate, chloralimide
Chlorpromazine and its salts
Disulfiram
Glutethimide, its salts and derivatives
Methamphetamine and any salt thereof
Paraldehyde and Metaldehyde
Pipradrol and any salt thereof
Promazine and its salts
Sulphonal and alkyl sulphonals

Part II

Adrenocorticotrophic Hormone,
    Corticotrophin
4-amino-N-methylpteroyl glutamic acid and its salts
Aminopterin
4-amino-pteroyl aspartic acid and its salts
Aminopyrine and any salt, homologue or derivative thereof
Antibiotics, the following:
    Carbomycin and any compound thereof
    Chloramphenicol
    Chlortetracyline and any salt or derivative thereof
    Cycloserine
    Dihydrostreptomycin and any compound thereof
    Erythromycin and any compound thereof
    Novobiocin, its salts and derivatives
    Oxytetracycline and any compound thereof
    Penicillin, its salts or derivatives
        or preparations thereof excluding lozenges that contain not more than 3,000 International Units per dose
    Polymyxin B Sulphate except for topical use or for local action in the oral cavity or nasal passages
    Streptomycin and any compound thereof
    Viomycin and any compound thereof

10, July 12, 1956.
Replaces page 10, May 30, 1956.

Anticoagulants, the following:
- Bishydroxycoumarin, its salts and derivatives
- Derivatives of 4-hydroxycoumarin when sold or recommended as anticoagulants
- Phenylindanedione

Busulfan
Cinchophen and Neocinchophen and their salts
Cortisone and any salt or derivative thereof
2, 4-dinitrophenol and any compound, homologue or derivative thereof
Ergot alkaloids
Hydantoin derivatives
Iproniazid
Isoniazid
6-mercaptopurine
Phenylbutazone
Primidone
Pyrazinamide
Selenium and any compound thereof
Sex hormones (except skin creams containing sex hormones, which are demonstrated to be free from systemic effects)
Sulphonamides and any salt, homologue, or derivative thereof
Thiocyanates
Thiouracil and any homologue, or derivative thereof
Thyroid
Thyroxin and any salt thereof
Tretamine
l-Triiodothyronine
Trimethadione and Paramethadione
Urethane

11, July 12, 1956.
Replaces page 11, May 30, 1956.

FOOD AND DRUG REGULATIONS

Made by Order in Council P.C. 1954-1915 of 8th December, 1954,
as amended by P.C. 1955-328 of 8th March, 1955,
by P.C. 1955-1093 of 21st July, 1955,
by P.C. 1956-567 of 12th April, 1956,
by P.C. 1956-871 of 7th June, 1956,
by P.C. 1956-1054 of 12th July, 1956,
by P.C. 1956-1148 of 26th July, 1956,
by P.C. 1956-1347 of 6th September, 1956,
by P.C 1956-1423 of 20th September, 1956, and
by P.C. 1956-1921 of 28th December, 1956.

12, December 28, 1956.
Replaces page 12, September 20, 1956.

Part A

Administration

General

A.01.001. These regulations may be cited as the Food and Drug Regulations.

A.01.002. These regulations, where applicable, prescribe the standards of composition, strength, potency, purity, quality or other property of the article of food, drug, cosmetic or device to which they refer.

Interpretation

A.01.010. In these regulations

(a) "acceptable method" means a method of analysis or examination indicated by the Director as acceptable for use in the administration of the Act,

(b) "Act" means the Food and Drugs Act,

(c) "cubic centimetre" and its abbreviation "cc." shall be deemed to be interchangeable with the term "millilitre" and its abbreviation "ml.",

(d) "Director" means the Director of the Food and Drug Divisions of the Department,

(e) "inner label" means the label on or affixed to an immediate container of a food, drug, cosmetic, or device,

(f) "Lot number[1]" means any combination of letters, figures, or both, by which any food or drug can be traced in manufacture and identified in distribution,

(g) "manufacturer", except in Division 3 and Division 4 of **Part C**, means a person who under his own name, or under a trade, design or word mark, trade name or other name, word or mark controlled by him sells a food, drug, cosmetic or device, and includes a firm, partnership, or corporation,

(h) "official method" means the method of analysis or examination designated by the Director for use in the administration of the Act,

(i) "outer label" means the label on or affixed to the outside of a package of a food, drug, cosmetic or device.

A.01.011. The Director shall, upon request, furnish copies of official methods.

A.01.012. The Director shall, upon request, indicate that a mehod is acceptable or otherwise upon its submission to him for a ruling.

Analysts[2]; Inspectors[3]

A.01.020. All designations as Dominion analysts prior to the coming into force of these regulations are hereby revoked and the members of the technical staff of the Department named in Appendix I[4] are hereby designated as analysts.

A.01.021. All designations as inspectors prior to the coming into force of these regulations are hereby revoked and the members of the staff of the Department named in Appendix II[5] are hereby designated as inspectors.

A.01.022. Inspectors shall perform the functions and duties, and carry out the responsibilities, prescribed by the Act, the regulations, and the Minister.

A.01.023. The authority of an inspector extends to and includes the whole of Canada.

A.01.024. A certificate that a person has been designated as an inspector shall be in the form set out therefor in Appendix III[6], shall be signed by the Deputy Minister of National Health or the Director and the person designated, and shall bear the seal of the Department.

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[1] The lot number should be preceded by the words "Lot number" or by "Lot No.", "Lot" or "(L.)".
[2] See pages 1 and 139
[3] See pages 1 and 140
[4] See page 139
[5] See page 140
[6] See page 141

13, May 30, 1956.
Replaces page 13.

A.01.025. Where authorized by regulation pursuant to the Canadian Broadcasting Act inspectors shall act as representatives of the Canadian Broadcasting Corporation for the purpose of enforcing the regulations thereof in respect to the advertising of a food, drug, cosmetic or device.

A.01.026. An inspector may take photographs of premises and articles to which the Act or regulations apply as defined in Section 21 of the Act as may be relevant to the administration of the Act or the regulations in so far as they apply to unsanitary conditions.

Importations

A.01.040. An inspector may examine, take specimens of and detain pending further examination any food, drug, cosmetic or device sought to be imported into Canada.

A.01.041. Where a specimen of a food, drug, cosmetic or device is taken as provided in A.01.040, the inspector shall forthwith submit the specimen to an analyst for examination or analysis.

A.01.042. Subject to A.01.043, where, as a result of an examination or analysis of a specimen of a food, drug, cosmetic or device, an analyst reports that the food, drug, cosmetic or device, would, if sold in Canada, constitute a violation of the Act or these regulations, the food, drug, cosmetic or device shall not be admitted into Canada for use as a food, drug, cosmetic or device, and the inspector shall send a report of analysis or examination to any Collector of Customs concerned and a copy to the importer.

A.01.043. Where a food, drug, cosmetic or device sought to be admitted into Canada, would, if sold in Canada, constitute a violation of the Act or these regulations, the food, drug, cosmetic or device may be admitted into Canada for the purpose of relabelling or reconditioning under the supervision of an inspector in compliance with such written conditions as may be specified in the report of an analyst, and where such relabelling or reconditioning is not satisfactorily carried out within three months after the report is made or such lesser period as may be specified in the report, such food, drug, cosmetic or device shall be exported and if not exported within a further period of three months shall be forfeited to the Crown and disposed of as the Minister may direct; but the Minister may extend the time for complying with conditions or for exporting the said goods.

Sampling

A.01.050. When taking a sample pursuant to Section 21 of the Act, an inspector shall, after procuring a suitable quantity of the article in question, notify the owner thereof or the person from whom the sample was obtained of his intention to submit a sample thereof to an analyst for analysis or examination, and

(a) where, in the opinion of the inspector, division of the procured quantity would not interfere with analysis or examination

(i) divide the quantity into three parts,

(ii) identify the three parts as the owner's portion, the sample, and the duplicate sample and where only one part bears the label, that part shall be identified as the sample,

(iii) seal each part in such a manner that it cannot be opened without breaking the seal and

(iv) deliver the part identified as the owner's portion to the owner or the person from whom the sample was obtained and forward the sample and the duplicate sample to an analyst for analysis or examination, or

(b) where, in the opinion of the inspector, division of the procured quantity would interfere with analysis or examination

(i) identify the entire quantity as the sample,

(ii) seal the sample in such a manner that it cannot be opened without breaking the seal, and

(iii) forward the sample to an analyst for analysis or examination.

A.01.051. Where the owner or the person from whom the sample was obtained objects to the procedure followed by an inspector under A.01.050 at the time the sample was obtained, the inspector shall follow both procedures set out in that section if the owner or the person from whom the sample was obtained supplies him with a sufficient quantity of the article.

Tariff of Fees

A.01.060. The cost of analysing a sample other than for the purpose of the Act, for a department of the Government of Canada for the purpose of legal action is fifteen dollars.

Part B

FOODS

Division 1

General

B.01.001. In this **Part**

(a) "common name" means, with reference to a food, the name of the food printed in boldface type in these regulations or, if the name of the food is not so printed, the name in English or French by which the food is generally known,

(b) "flavouring preparation" includes any food for which a standard is provided in Division 10,

(c) "food colour" means those colours permitted for use in or upon food by Division 6,

(d) "gelling agent" includes any food for which a standard is provided in Division 12,

(e) "per cent" means per cent by weight unless otherwise stated, and

(f) "sweetening agent" includes any food for which a standard is provided in Division 18.

B.01.002. Except as provided in B.01.007, no person shall sell a food that is not labelled as required by these regulations.

B.01.003. Except as provided in these regulations, the label[1] of a package of food shall carry

(a) on the main panel of the label[1]

(i) the common name of the food,

(ii) a declaration by name of any Class II[2], Class III[3], or Class IV[4] preservative therein.

(iii) a declaration of any food colour[5] added thereto, and

(iv) a declaration of any artificial or imitation flavouring preparation added thereto,

(b) on the label[1]

(i) the name and address of the manufacturer[6] of the food,

(ii) in the case of a food consisting of more than one ingredient and for which no standard is prescribed in these regulations for the food, a complete list of the ingredients by their common names in descending order of their proportions unless the quantity of each ingredient is stated in terms of percentage or proportionate composition,

(iii) except in the case of a food, the weight of which including the package in which it is contained is under two ounces, a correct statement of the net content in terms of weight, measure, or number in compliance with good commercial practice.

B.01.004. Any statement or information required by these regulations to be carried on a label[1] shall be legibly and conspicuously displayed thereon.

B.01.005. Where inner and outer labels are employed on a package of food, all label declarations required by these regulations shall appear on both the inner and the outer labels except that the statement of contents need not appear on the inner label.

B.01.006. No reference, direct or indirect, to the Act or to these regulations shall be made upon any label[1] of, or in any advertisement for, a food.

B.01.007. The provisions of B.01.003 do not apply to a food packaged from bulk on the premises where the food is retailed but where a package of food bears a statement, mark, or device regarding the ingredients or the substances contained therein, in addition to

(a) the name of the food,

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[1] See page 1, A.01.010 (*e*) (*i*), B.01.005.
[2] See B.16.007.
[3] See B.16.011.
[4] See B.16.013.
[5] See B.01.008; .009, B.06
[6] See A.01.010 (*g*).

(b) the name and address of the retailer, and

(c) the net contents,

it shall be labelled as required by the Act and these regulations.

B.01.008. Notwithstanding B.01.003 *(a)* (iii), food colour[1] may be used without label declaration, in or upon

bakery products, except brown bread,
butter,
cheese and process cheese,
confectionery,
gelatine desserts,
ice cream,
icing sugar,
liqueurs and alcoholic cordials,
sherbet,
smoked fish, and
soft drinks.

B.01.009. Notwithstanding B.01.003 *(a)* (iii), caramel may be used without label declaration, to colour

non-excisable fermented beverages,
sauces,
spirituous liquors except gin,
vinegar, except spirit vinegar or blends containing spirit vinegar, and
wine.

B.01.010. Notwithstanding B.01.003 *(b)* (ii), a list of ingredients is not required for

bakery products,
black pudding,
blood pudding,
confectionery,
flavouring preparations,
gelatine desserts,
non-nutritive seasoning sauces,
pastry spice,
pickling spice,
poultry seasoning,
preparations of coal tar colours,
soft drinks,
soups, and
white pudding,

unless an ingredient is mentioned on the label[2] of, or in an advertisement for any food or class of food referred to in this section that is not

(a) included in the common name of the food,

(b) used to distinguish the food, or

(c) required by these regulations to be declared.

B.01.011. Where by any statute of the Parliament of Canada or any regulation made thereunder a standard or grade is prescribed for a food and that standard is given a name or designation by such statute or regulation, no person shall on a label[2] of or in any advertisement for that food use that name or designation unless the food conforms with the standard or grade.

B.01.012. Where a statement or claim implying a special dietary use is made on the label[2] of, or in any advertisement for a food, the label shall carry a statement of the type of diet for which the food is recommended.

B.01.013. Where a statement or claim implying a low sodium content is made on the label[2] of, or in any advertisement for a food, the label shall carry a declaration of the sodium content in milligrams per 100 grams.

B.01.014. Where a statement or claim relating to the caloric content is made on the label[2] of, or in any advertisement for a food, the label shall carry a statement of the caloric content in calories per 100 grams.

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[1] See B.06.
[2] See page 1, A.01.010 *(s)* *(i)*. B.01.005.

B.01.015. A food containing saccharin, or sodium or calcium salts of cyclohexyl sulphamic acid shall carry on the main panel of the label[1] a declaration by name of the presence thereof and on the label, the statement "Contains (naming the synthetic sweetener) and should be used only on the advice of a physician".

B.01.016. Where a standard for a food is provided in these regulations only those ingredients named in the standard shall be used in the food.

B.01.017. A food is adulterated if any of the following substances or classes of substances in present therein or has been added thereto:

(a) mineral oil, paraffin wax, or any preparation of these,

(b) coumarin, or an extract of tonka beans, the seed of *Dipteryx odorata* Willd. or *Dipteryx oppositifolia* Willd., or

(c) synthetic sweetening agents other than saccharin, or sodium or calcium salts of cyclohexyl sulphamic acid.

B.01.018. Notwithstanding B.01.017,

(a) a food is not adulterated by reason only that it contains mineral oil not exceeding 0·3 per cent if good manufacturing practice requires its use, and

(b) chewing gum is not adulterated by reason only that it contains a paraffin wax base.

B.01.019. Subject to B.01.020, where the contents of a package of food are expressed in terms of weight, measure, or number, no variations from the quantity declared on the label[1] are permitted other than the following

(a) variations due exclusively to weighing, measuring, or counting that occur in packaging conducted in accordance with good commercial practice, but not to be such that the average content is less than the quantity declared on the label[1], as determined by the official method[2].

(b) variations due exclusively to differences in the capacity of containers resulting solely from unavoidable difficulties in manufacturing, but no greater variation is permitted because of the design of the containers than is permitted in the case of containers of similar capacity that can be manufactured so as to be of approximately uniform capacity, and

(c) variations in weight or measure that unavoidably result from the ordinary and customary exposure of the package to evaporation or to the absorption of water under normal atmospheric conditions.

B.01.020. Notwithstanding B.01.019, where the contents of a package of food are expressed in terms of minimum weight, measure, or number, the contents of the package shall not be less than the minimum expressed.

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[1] See page 1, A.01.010 (*e*) (*i*), B. 01.005.
[2] See A.01.010 (*h*).

Division 2

Alcoholic Beverages

B.02.001. The foods referred to in this Division are included in the term *alcoholic beverage*

B.02.002. In this Division

(a) "alcohol" means ethyl alcohol,

(b) "absolute alcohol" means alcohol of a strength of 100 per cent,

(c) "malt-wine" means an alcoholic distillate obtained by pot-still distillation from a mash of cereal grain or cereal grain products saccharified by the diastase of malt and fermented by the action of yeast,

(d) "grain spirit" means an alcoholic distillate, obtained from a mash of cereal grain or cereal grain products saccharified by the diastase of malt or by other natural enzyme and fermented by the action of yeast, and from which all or nearly all of the naturally occurring substances other than alcohol and water have been removed,

(e) "molasses spirit" means an alcoholic distillate, obtained from sugar-cane by-products fermented by the action of yeast, from which all or nearly all of the naturally occurring substances other than alcohol and water have been removed,

(f) "age" means the period during which an alcoholic beverage is kept under such conditions of storage as may be necessary to render it potable or to develop its characteristic flavour or bouquet,

(g) "flavouring" means other domestic or imported spirits or wine as permitted by regulations made under the authority of the Excise Act,

(h) "peat-dried malt" means barley malt that has been kilned over fires of peat with or without a mixture of other fuels,

(i) "small wood" means wood casks or barrels of not greater than 150 gallon capacity.

B.02.003. No person shall sell[1] a distilled alcoholic beverage that contains less than 39·94 per cent by volume of absolute alcohol unless the main panel of the label[2] carries a declaration of the actual percentage by volume of absolute alcohol contained in such distilled alcoholic beverage.

Whisky

B.02.010. Whisky shall be a potable alcoholic distillate, obtained from a mash of cereal grain or cereal grain products saccharified by the diastase of malt or other natural enzyme and fermented by the action of yeast, with or without the addition of flavouring[3], or caramel[4].

B.02.011. No person shall sell whisky for consumption in Canada that has not been aged and held for a period of not less than two years in small wood.

B.02.012. No person shall make any claim for the age of whisky other than for the period during which the whisky has been stored in small wood, but in the case of whisky that has been aged in small wood for not less than two years, any period not exceeding six months during which the whisky is held in other containers may be claimed as age.

B.02.013. Malt whisky derived from peat-dried malt shall be whisky, obtained by the pot-still distillation of a mash of peat-dried malt fermented by the action of yeast, or a mixture of such whiskies, and shall possess the aroma, taste, and character generally attributed to malt whisky from peat-dried malt.

B.02.014. Malt whisky derived from other than peat-dried malt shall be whisky, obtained by the pot-still distillation of a mash consisting substantially of barley malt fermented by the action of yeast, or a mixture of such whiskies.

B.02.015. Grain whisky shall be whisky that has been distilled in such a manner as to retain some of the volatile congeneric substances produced during fermentation.

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[1] See page 1.
[2] See page 1, A.01.010 (*e*) (*i*), B.01.005.
[3] See B.02.002 (*g*).
[4] See B.01.009.

B.02.016. **Scotch Whisky** shall be whisky distilled in Scotland as Scotch whisky for domestic consumption in accordance with the laws of the United Kingdom.

B.02.017. No person shall blend or modify in any manner any Scotch whisky that is imported in bulk for the purpose of bottling and sale in Canada as Scotch whisky except by

(a) blending with other Scotch whisky,

(b) the addition of distilled or otherwise purified water to adjust to a required strength, or

(c) the addition of caramel[1].

B.02.018. **Irish Whisky** shall be whisky distilled in Northern Ireland or in the Republic of Ireland as Irish whisky for domestic consumption in accordance with the laws of Northern Ireland or the Republic of Ireland.

B.02.019. No person shall blend or modify in any manner any Irish whisky that is imported in bulk for the purpose of bottling and sale in Canada as Irish whisky except by

(a) blending with other Irish whisky,

(b) the addition of distilled or otherwise purified water to adjust to a required strength, or

(c) the addition of caramel.[1]

B.02.020. **Canadian Whisky (Canadian Rye Whisky, Rye Whisky)** shall be whisky distilled in Canada, and shall possess the aroma, taste and character generally attributed to Canadian whisky.

B.02.021. **Highland Whisky** shall be whisky manufactured and blended in Canada and shall consist of a blend of

(a) malt whisky from peat-dried malt that has been distilled in Canada or in Scotland, and

(b) grain whisky

and shall contain not less than 25 per cent of such malt whisky at proof and if 51 per cent or more of the malt whisky so used is distilled in Scotland, the label[2] of or advertisement for the Highland whisky may include a statement to the effect that it contains malt whisky distilled in Scotland.

Rum

B.02.030. **Rum** shall be a potable alcoholic distillate obtained from sugar-cane products fermented by the action of yeast or a mixture of yeast and other organisms, or a mixture of such distillates, with or without caramel,[1] and may be flavoured with fruit or other botanical substances or flavouring.[3]

B.02.031. No person shall sell[4] for consumption in Canada rum that has not been aged and held for a period of not less than two years in small wood.

B.02.032. No person shall make any claim for the age of rum other than for the period during which the rum has been stored in small wood, but in the case of rum that has been aged in small wood for not less than two years, any period not exceeding six months during which the rum is held in other containers may be claimed as age.

B.02.033. No person shall blend or modify in any manner any rum that is imported in bulk for the purpose of bottling and sale in Canada as imported rum except by

(a) blending with other imported rum,

(b) the addition of distilled or otherwise purified water to adjust to a required strength, or

(c) the addition of caramel.[1]

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[1] See B.01.009.
[2] See page 1, A.01.010 (*e*) (*i*), B.01.005.
[3] See B.02.002.
[4] See page 1.

Gin

B.02.040. Hollands (Hollands Gin, Geneva, Geneva Gin, Genever, Genever Gin, Dutch-type Gin) shall be a potable alcoholic beverage obtained by

(a) the redistillation of malt-wine with or over juniper berries with or without other aromatic botanical substances, or a combination of such redistillations, and that may be labelled or advertised as being *distilled*,

(b) the redistillation of a combination of malt-wine and not more than four times its volume at proof of grain spirit with or over juniper berries with or without other aromatic botanical substances, or a combination of such redistillations, and that may be labelled or advertised as being *distilled*, or

(c) the blending of malt-wine, distilled with or over juniper berries with or without other aromatic botanical substances, and not more than four times its volume at proof of grain or molasses spirit, or a combination of such blendings, and that shall be labelled and advertised as *blended gin*.

B.02.041. Gin, other than Hollands (Hollands Gin, Geneva, Geneva Gin, Genever, Genever Gin, Dutch-type Gin) shall be the product obtained by the redistillation of suitably rectified grain spirit with or over juniper berries with or without other aromatic botanical substances, and may contain sugar.

B.02.042. Dry Gin shall be gin to which no sugar has been added.

B.02.043. No person shall make any claim for age for gin but gin that has been held in suitable containers may bear a label declaration to that effect.

Brandy

B.02.050. Brandy shall be a potable alcoholic distillate obtained by the distillation of wine in the manufacture of which no additional sugar has been used, or a mixture of such distillates.

B.02.051. No person shall sell[1] brandy for consumption in Canada that has not been aged and held for a period of not less than two years in small wood.

B.02.052. No person shall make any claim for the age of brandy other than for the period during which it has been held in small wood.

B.02.053. Brandy shall be manufactured in accordance with the laws of the country of origin for domestic consumption and the label[2] shall clearly indicate such country of origin.

B.02.054. Cognac Brandy (Cognac) shall be brandy manufactured in the Cognac district of France in accordance with the laws of the French Republic for consumption in that country.

B.02.055. Armagnac Brandy (Armagnac) shall be brandy manufactured in the Armagnac district of France in accordance with the laws of the French Republic for consumption in that country.

B.02.056. Fruit Brandy, (naming the fruit) Brandy shall be a potable alcoholic distillate obtained by the distillation of

(a) fruit wine or a mixture of fruit wines,

(b) a mixture of wine and fruit wine, or

(c) a fermented mash of sound ripe fruit or mixture of fruits,

or a mixture of such distillates.

B.02.057. No person shall blend or modify in any manner any brandy that is imported in bulk for the purpose of bottling and sale in Canada as imported brandy except by

(a) blending with other imported brandy,

(b) the addition of distilled or otherwise purified water to adjust to a required strength, or

(c) the addition of caramel.[3]

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[1] See page 1.
[2] See page 1, A.01.010 (*s*) (*i*), B.01.005.
[3] See B.01.009.

Liqueurs and Alcoholic Cordials

B.02.060. Liqueurs and alcoholic cordials shall be products obtained by the mixing or distillation of grain spirit, brandy, or other distilled spirits with or over fruits, flowers, leaves or other botanical substances or their juices, or with extracts derived by infusion, percolation, or maceration of such botanical substances with or without natural or artificial flavouring preparation[1] and colour,[2] to which sucrose or dextrose or both have been added in an amount not less than 2·5 per cent of the finished product.

Wine

B.02.100. **Wine** shall be the product of the alcoholic fermentation of the juice of the grape to which during the course of manufacture may be added any of the following

(a) yeast,

(b) concentrated grape juice,

(c) sugar, dextrose, or invert sugar, or aqueous solutions of any of these,

(d) yeast foods,

(e) calcium sulphate in such quantity that the content of soluble sulphates in the finished wine shall not exceed 0·2 per cent weight by volume calculated as potassium sulphate,

(f) calcium carbonate in such quantity that the content of tartaric acid in the finished wine shall not be less than 0·15 per cent weight by volume,

(g) sulphurous acid including salts thereof in such quantity that its content in the finished wine shall not exceed

(i) 70 parts per million in the free state or

(ii) 350 parts per million in the combined state

calculated as sulphur dioxide,

(h) tartaric or citric acid,

(i) pectic enzymes,

(j) fining agent namely, isinglass, gelatin, white of egg, casein, albumen, clay, tannin, or edible dried blood that is the subject of a certificate under the Meat and Canned Foods Act,

(k) caramel,[3]

(l) brandy, or wine spirit, or

(m) carbon dioxide.

B.02.101. No person shall sell[4] wine that contains more than 0·13 per cent weight by volume of volatile acid calculated as acetic acid as determined by the official method.[5]

B.02.102. Wine spirit shall be an alcoholic distillate obtained from wine or from grape pomace.

B.02.103. **Fruit Wine, (naming the fruit) Wine** shall be the product of the alcoholic fermentation of the juice of sound ripe fruit other than grape.

B.02.104. **Vermouth** shall be wine to which has been added bitters, aromatics or other botanical substances, or flavouring preparations, and may contain

(a) caramel,[3]

(b) sugar, dextrose, or invert sugar, or

(c) brandy, or wine spirit

and shall contain not more than 20 per cent absolute alcohol by volume.

B.02.105. **Wine Cocktail** shall be wine to which has been added flavouring preparation,[1] and may contain

(a) caramel,[3]

(b) sugar, dextrose, or invert sugar, or

(c) brandy, or wine spirit

and shall contain not more than 20 per cent absolute alcohol by volume.

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[1] See B.10.
[2] See B.06.
[3] See B.01.009.
[4] See page 1.
[5] See A.01.010) (*b*).

B.02.106. **Honey Wine** shall be the product of the alcoholic fermentation of honey, with or without the addition of caramel, natural botanical flavours, and honey spirit.

Cider

B.02.120. **Cider** shall be the product of the alcoholic fermentation of apple juice or of apple juice to which has been added not more than 10 per cent weight by volume of sugar, dextrose, or invert sugar, and shall contain not more than 7 per cent absolute alcohol by volume, and 100 millilitres of cider measured at a temperature of 20°C. shall

(a) contain not less than 2 grams and not more than 12 grams of total solids,

(b) contain not more than 8 grams of sugar calculated as reducing sugars, and

(c) yield not less than 0·2 gram and not more than 0·4 gram of cider ash.

B.02.121. **Sparkling Cider** shall be cider that is impregnated either naturally or artificially with carbon dioxide under pressure.

B.02.122. **Champagne Cider** shall be cider that is impregnated with carbon dioxide under pressure by

(a) conducting the afterpart of the fermentation in closed vessels or

(b) secondary fermentation in closed vessels with or without the addition of sugar, dextrose, or invert sugar,

and notwithstanding B.02.120 shall contain not less than 7 per cent and not more than 13 per cent absolute alcohol by volume.

B.02.123. No person shall sell[1] cider or champagne cider that has more than 0·2 per cent weight by volume of volatile acidity calculated as acetic acid as determined by the official method.[2]

Malt Liquors

B.02.130. Malt liquor shall be the alcoholic beverage made by the alcoholic fermentation of an infusion, in potable water, of barley malt and hops that may also contain other malted cereal grain and starchy or saccharine matter, and may be subsequently pasteurized.

B.02.131. **Ale** shall be malt liquor brewed in such a manner as to possess the aroma, taste, and character commonly attributed to ale, and shall contain not less than 3·2 per cent absolute alcohol, and 100 millilitres of ale measured at a temperature of 20°C. shall contain not less than 3·5 grams of extractive matter and shall yield not less than 0·12 gram of ash.

B.02.132. **Beer** shall be malt liquor brewed in such a manner as to possess the aroma, taste, and character commonly attributed to beer, and shall contain not less than 3·2 per cent absolute alcohol, and 100 millilitres of beer measured at a temperature of 20°C. shall contain not less than 3·5 grams of extractive matter and shall yield not less than 0·12 gram of ash.

B.02.133. **Light Beer** shall be beer that contains not less than 0·96 and not more than 2·0 per cent absolute alcohol, and notwithstanding B.02.132, 100 millilitres of light beer measured at a temperature of 20°C. may yield less than 0·12 gram of ash.

B.02.134. **Stout** shall be malt liquor brewed in such a manner as to possess the aroma, taste, and character commonly attributed to stout and to a marked degree the flavour of hops, and shall contain not less than 3·2 per cent absolute alcohol, and 100 millilitres of stout measured at a temperature of 20°C. shall contain not less than 5·0 grams of extractive matter and shall yield not less than 0·15 gram of ash.

B.02.135. **Porter** shall be malt liquor brewed in the manner used in the brewing of stout so as to possess the aroma, taste, and character commonly attributed to porter but having in comparison with stout a less marked flavour of hops, and shall contain not less than 3·2 per cent absolute alcohol, and 100 millilitres of porter measured at a temperature of 20°C. shall contain not less than 4·0 grams of extractive matter and shall yield not less than 0·13 gram of ash.

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[1] See page 1.
[2] See A.01.010 (h).

Baking Powder

B.03.001. **Baking Powder** shall be a combination of sodium bicarbonate, an acid-reacting material mentioned in B.03.002 and starch or other neutral material, and shall yield not less than 10 per cent of its weight of carbon dioxide as determined by the official method.

B.03.002. The acid-reacting material of baking powder shall be

(a) tartaric acid or its salts, or both,

(b) acid salts of phosphoric acids, or

(c) acid compounds of aluminium.

[1] See A.01.010 (*h*).

Cacao Products

B.04.001. The foods referred to in this DIVISION shall be derived from cacao beans and are included within the term *cacao product.*

B.04.002. **Cacao Beans (Cocoa Beans)** shall be the seeds *of Theobroma cacao* L., or closely related species.

B.04.003. **Cacao Nibs (Cocoa Nibs, Cracked Cocoa)** shall be prepared by heating and cracking cleaned, dried or cured cacao beans and removing the shell therefrom.

B.04.004. **Chocolate (Plain Chocolate, Bitter Chocolate, Chocolate Liquor)** shall be obtained by grinding cacao nibs, and shall contain not less than 50 per cent cacao butter,[1] and on the dry and fat-free basis may contain not more than

(a) 7 per cent crude fibre,

(b) 8 per cent total ash, and

(c) 0·4 per cent ash insoluble in hydrochloric acid.

B.04.005. Cacao products may be processed with hydroxides, carbonates, or bicarbonates of sodium, potassium, or magnesium.

B.04.006. No person shall sell[2] a cacao product that is processed with hydroxides, carbonates, or bicarbonates of sodium, potassium, or magnesium unless

(a) the label[2] carries, immediately preceding or following the name of the cacao product, and without intervening written, printed, or graphic matter, the phrase "Processed with Alkali", or the phrase "Alkali Treated"; and

(b) the total weight of such processing agents used with each one hundred parts by weight of cacao nibs used in the preparation of such cacao product is not greater in neutralizing value, calculated from the respective combining weights of such processing agents, than the neutralizing value of three parts by weight of anhydrous potassium carbonate.

B.04.007. The ash limits provided for cacao products in this DIVISION may be increased for cacao products processed with alkali as provided in B.04.006 by the amount of ash from the processing agent used.

B.04.008. **Sweet Chocolate (Sweet Chocolate Coating)** shall be chocolate mixed with sugar or with a combination of not less than 75 per cent sugar and not more than 25 per cent dextrose, with or without the addition of cacao butter,[1] spices, other flavouring material,[2] or of not more than 0·5 per cent, of the finished product, of emulsifier; and may contain on the dry, sugar-free, and fat-free basis no greater proportion of crude fibre, total ash, or ash insoluble in hydrochloric acid respectively than does chocolate on the dry, fat-free basis.

B.04.009. **Milk Chocolate (Sweet Milk Chocolate, Milk Chocolate Coating, Sweet Milk Chocolate Coating)** shall be the cacao product obtained from chocolate by grinding with sugar or with a combination of not less than 75 per cent sugar and not more than 25 per cent dextrose, with or without the addition of cacao butter, spices, other flavouring material, or of not more than 0·5 per cent, of the finished product, of emulsifier; and shall contain in the finished product not less than 12 per cent milk solids which shall be in the proportions that are normal to whole milk.

B.04.010. **Cocoa (Powdered Cocoa)** shall be chocolate from which part of the cacao butter[1] has been removed, and shall contain on the dry, fat-free basis no greater proportion of crude fibre, total ash, or ash insoluble in hydrochloric acid respectively than does chocolate on the dry, fat-free basis, and where cocoa contains

(a) 22 per cent or more cacao butter[1] it may be designated **Breakfast Cocoa,** and

(b) less than 10 per cent cacao butter[1] it shall be designated **Low Fat Cocoa.**

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[1] See B.09.005.
[2] See B.01.017, B.10.

Coffee

B.05.001. Green Coffee (Raw Coffee, Unroasted Coffee) shall be the seed of *Coffea arabica* L., *C. liberica* Hiern, or *C. robusta* Chev., freed from all but a small portion of its spermoderm.

B.05.002. Roasted Coffee (Coffee) shall be roasted green coffee, and shall contain not less than 10 per cent fat, and may contain not more than 6 per cent total ash.

B.05.003. No person shall sell[1] decaffeinated coffee unless the percentage of the caffeine content removed is stated on the label,[2] and the finished product contains no ingredient other than those normally present in coffee.

[1] See page 1.
[2] See page 1, A.01.010 (*s*) (*i*), B.01.005.

Division 6

Food Colours

B.06.001. In this Division

(a) "pure dye" means the coal tar dye contained in a coal tar colour exclusive of any impurity or diluent,

(b) "diluent" means any substance other than pure dye present in a coal tar colour, mixture, or preparation,

(c) "mixture" means a mixture of two or more coal tar colours or a mixture of one or more coal tar colours with one or more diluents,

(d) "preparation" means a preparation of one or more coal tar colours containing less than 15 per cent pure dye and sold for household use in containers of two ounces net or less.

B.06.002. No person shall sell[1] for use in or upon food any colour other than the following:

(a) natural colours, being cochineal, vegetable colours and vegetable colour extractives,

(b) caramel,

(c) specially purified charcoals, carbon blacks, and iron oxide,

(d) coal tar colours for which a standard is provided in B.06.021 to B.06.038.

B.06.003. No person shall sell a food having in or upon it any added colour other than the following:

(a) natural colours, being cochineal, vegetable colours and vegetable colour extractives,

(b) caramel,

(c) specially purified charcoals, carbon blacks, and iron oxide,

(d) coal tar colours for which a standard is provided in B.06.021 to B.06.038.

B.06.004. No person shall sell[1] a food other than a coal tar colour, having in or upon it an added coal tar colour for which a standard is provided in B.06.021 to B.06.038, if the proportion thereof exceeds one part by weight of coal tar colour to each thirty-five hundred parts by weight of food, as prepared for consumption according to label direction.

B.06.005. No person shall sell[1] a colour for use in or upon food that contains more than

(a) 2 parts per million of arsenic, calculated as arsenic,

(b) 10 parts per million of lead, calculated as lead,

as determined by the official method,[2] or

(c) except in the case of iron oxide, a total of 100 parts per million of iron and copper, calculated as iron and copper,

and if other heavy metals are present the colour shall be deemed to be adulterated.

B.06.006. No person shall sell a coal tar colour for use in or upon food unless the label[3] carries

(a) the common name of the coal tar colour,

(b) the lot number[4] of the coal tar colour, and

(c) the words "Food Colour".

B.06.007. No person shall sell[1] a mixture for use in or upon food unless the label[3] carries

(a) the lot number[4] of the mixture, and

(b) the words "Food Colour".

B.06.008. No person shall sell[1] a preparation for use in or upon food unless

(a) the lot number[4] of the coal tar colour contained in the preparation or an identifying code number allotted to the preparation by the manufacturer[5] and filed with the Food and Drug Divisions, Ottawa, is declared on the invoice accompanying the shipment to the retailer, and

(b) the label[3] carries the words "Food Colour Preparation".

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[1] See page 1.
[2] See A.01.010 (*h*).
[3] See page 1, A.01.010 (*s*) (*t*), B.01.005.
[4] The lot number should be preceded by the words "Lot Number" or by "Lot No.", "Lot" or "(L)".
[5] See A.01.010 (*g*).

B.06.009. No person shall import or sell[1] a coal tar colour for use in or upon food unless it has been certified by the Director, or by another agency acceptable to the Director, that each lot meets the requirement of B.06.005, and the standard for such colour as established in B.06.021 to B.06.038 and if certified by an agency, a copy of the certificate has been submitted to and approved by the Director.

B.06.010. No person shall import or sell[1] a mixture or a preparation of food colour for use in or upon food unless

(a) it has been certified by the Director, or by another agency acceptable to the Director, that any coal tar colour contained therein meets the requirement of B.06.005, and the standard for such colour as established in B.06.021 to B.06.038, or

(b) the coal tar colour has been previously certified by the Director, or by another agency acceptable to the Director,

and if certified by an agency, a copy of the certificate has been submitted to and approved by the Director, and

(c) the diluent meets the requirements of B.06.005.

Coal Tar Colours

B.06.021. Amaranth shall be the trisodium salt of 1-(4-sulpho-1-naphthylazo)-2-naphthol-3, 6-disulphonic acid, and shall contain not less than 75 per cent pure dye, and may contain not more than

(a) 0·5 per cent water insoluble matter,

(b) 0·4 per cent combined ether extracts,

(c) 1·0 per cent mixed oxides, and

(d) 4·0 per cent subsidiary dyes, calculated as Fast Red E.

B.06.022. Ponceau 3R shall be the disodium salt of 1-pseudocumylazo-2-naphthol-3, 6-disulphonic acid, and shall contain not less than 83 per cent pure dye, and may contain not more than

(a) 0·5 per cent water insoluble matter,

(b) 0·4 per cent combined ether extracts,

(c) 0·2 per cent pseudo-cumidine,

(d) 1·0 per cent mixed oxides, and

(e) 5·0 per cent lower sulphonated dyes,

and the boiling range of the pseudo-cumidine obtained by reduction of the dye shall be between 220°C. and 245°C.

B.06.023. Erythrosine shall be the disodium salt of 9-*o*-carboxyphenyl-6-hydroxy-2, 4, 5, 7-tetraiodo-3-isoxanthone, and shall contain not less than 83 per cent pure dye, and may contain not more than

(a) 0·4 per cent water insoluble matter,

(b) 0·2 per cent combined ether extracts, and

(c) 1·0 per cent mixed oxides,

and the organically combined iodine in the anhydrous pure dye shall be not less than 56·8 per cent and not more than 58·5 per cent.

B.06.024. Ponceau SX shall be the disodium salt of 2-(5-sulpho-2, 4-xylylazo)-1-naphthol-4-sulphonic acid, and shall contain not less than 80 per cent pure dye, and may contain not more than

(a) 0·5 per cent water insoluble matter,

(b) 0·4 per cent combined ether extracts,

(c) 1·0 per cent mixed oxides, and

(d) 5·0 per cent subsidiary dyes.

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[1] See page 1.

B.06.025. REVOKED P.C. 1956-1148 of 26 July 1956.

B.06.026. REVOKED P.C. 1956-1148 of 26 July 1956.

B.06.027. REVOKED P.C. 1956-1148 of 26 July 1956.

B.06.028. **Naphthol Yellow S** shall be the disodium or dipotassium salt of 2, 4-dinitro-1-naphthol-7-sulphonic acid, and shall contain not less than 85 per cent pure dye, and may contain not more than

(a) 0·4 per cent water insoluble matter,

(b) 0·4 per cent combined ether extracts,

(c) 1·0 per cent mixed oxides, and

(d) 0·03 per cent Martius Yellow.

B.06.029. **Oil Yellow AB** shall be 1-phenylazo-2-naphthylamine, and shall contain not less than 99 per cent pure dye, and may contain not more than

(a) 0·5 per cent water soluble matter,

(b) 0·5 per cent carbon tetrachloride insoluble matter,

(c) 0·05 per cent intermediates, and

(d) 0·3 per cent sulphated ash,

and its melting point shall not be below 99°C.

B.06.030. **Oil Yellow OB** shall be 1-*o*-tolylazo-2-naphthylamine, and shall contain not less than 99 per cent pure dye, and may contain not more than

(a) 0·5 per cent water soluble matter,

(b) 0·5 per cent carbon tetrachloride insoluble matter,

(c) 0·05 per cent intermediates, and

(d) 0·3 per cent sulphated ash,

and its melting point shall not be below 120°C.

B.06.031. **Tartrazine** shall be the trisodium salt of 3-carboxy-5-hydroxy-1-*p*-sulphophenyl-4-*p*-sulphophenylazopyrazole, and shall contain not less than 75 per cent pure dye, and may contain not more than

(a) 0·5 per cent water insoluble matter,

(b) 0·5 per cent combined ether extracts,

(c) 0·1 per cent phenylhydrazine-*p*-sulphonic acid,

(d) 1·0 per cent mixed oxides, and

(e) 3·0 per cent subsidiary dyes.

B.06.032. Sunset Yellow FCF shall be the disodium salt of 1-*p*-sulphophenylazo-2-naphthol-6-sulphonic acid, and shall contain not less than 75 per cent pure dye, and may contain not more than

(a) 0·5 per cent water insoluble matter,

(b) 0·4 per cent combined ether extracts,

(c) 1·0 per cent mixed oxides, and

(d) 5·0 per cent subsidiary dyes.

B.06.033. Light Green SF Yellowish shall be the disodium salt of 4-{[4-(N-ethyl-*p*-sulphobenzylamino)-phenyl] – (4-sulphoniumphenyl)-methylene} – [1-(N-ethyl-N-*p*-sulphobenzyl)-$\triangle^{2,5}$-cyclohexadienimine], and shall contain not less than 79 per cent pure dye, and may contain not more than

(a) 0·5 per cent water insoluble matter,

(b) 0·4 per cent combined ether extracts,

(c) 1·0 per cent mixed oxides, and

(d) 5·0 per cent subsidiary dyes, calculated as Guinea Green B.

B.06.034. Guinea Green B shall be the monosodium salt of 4-[4-(N-ethyl-*p*-sulphobenzylamino)-diphenylmethylene] – [1-(N-ethyl-N-*p*-sulphoniumbenzyl)-$\triangle^{2,5}$-cyclohexadienimine], and shall contain not less than 82 per cent pure dye, and may contain not more than

(a) 0·5 per cent water insoluble matter,

(b) 0·4 per cent combined ether extracts, and

(c) 1·0 per cent mixed oxides

B.06.035. Fast Green FCF shall be the disodium salt of 4-{[4-(N-ethyl-*p*-sulphobenzylamino)-phenyl] – (4-hydroxy-2-sulphoniumphenyl)-methylene} – [1-(N-ethyl-N-*p*-sulphobenzyl)-$\triangle^{2,5}$-cyclohexadienimine], and shall contain not less than 85 per cent pure dye, and may contain not more than

(a) 0·5 per cent water insoluble matter,

(b) 0·4 per cent combined ether extracts,

(c) 1·0 per cent mixed oxides, and

(d) 5·0 per cent subsidiary dyes.

B.06.036. Indigotine shall be the disodium salt of indigotine-5, 5′-disulphonic acid, and shall contain not less than 87 per cent pure dye, and may contain not more than

(a) 0·5 per cent water insoluble matter,

(b) 0·5 per cent combined ether extracts,

(c) 1·0 per cent mixed oxides, and

(d) 5·0 per cent lower sulphonated dyes.

B.06.037. Brilliant Blue FCF shall be the disodium salt of 4-{[4-(N-ethyl-*p*-sulphobenzylamino)-phenyl] – (2-sulphoniumphenyl)-methylene} – [1-(N-ethyl-N-*p*-sulphobenzyl)-$\triangle^{2,5}$-cyclohexadienimine], and shall contain not less than 82 per cent pure dye, and may contain not more than

(a) 0·5 per cent water insoluble matter,

(b) 0·4 per cent combined ether extracts,

(c) 1·0 per cent mixed oxides, and

(d) 5·0 per cent subsidiary dyes.

B.06.038. Benzyl Violet 4B shall be the monosodium salt of 4-{[4-(N-ethyl-*p*-sulphobenzylamino)-phenyl] – [4-(N-ethyl-*p*-sulphonium benzylamino)-phenyl]-methylene} – (N, N-

dimethyl-$\triangle^{2,5}$-cyclohexadienimine), and shall contain not less than 85 per cent pure dye, and may contain not more than

(a) 8·0 per cent volatile matter at 135°C.,

(b) 0·3 per cent water insoluble matter,

(c) 0·4 per cent combined ether extracts,

(d) 0·2 per cent *p*-dimethylaminobenzoic acid,

(e) 4·0 per cent chloride and sulphate of sodium,

(f) 1·0 per cent mixed oxides,

and the sum of the volatile matter, chloride and sulphate of sodium, pure dye and leuco base of the dye shall be not less than 95 per cent.

B.06.050. The lake of any water soluble coal tar colour for which a standard is provided in B.06.021 to B.06.038 shall be the calcium or aluminium salt of the respective colour extended upon alumina.

B.06.051. The constants and percentages of components referred to in B.06.021 to B.06.038 shall be determined by the official method.[1]

[1] See A.01.010 (*h*).

Spices, Dressings and Seasonings

B.07.001. Cloves, whole or ground, shall be the dried flower buds of the clove plant, and may contain not more than

(a) 5 per cent clove stems,

(b) 8 per cent total ash,

(c) 0·5 per cent ash insoluble in hydrochloric acid, and

(d) 10 per cent crude fibre,

and shall contain not less than 15 per cent volatile ether extract.

B.07.002. Ginger, whole or ground, shall be the washed and dried or decorticated and dried rhizome of the ginger plant, and may contain not more than 10 per cent moisture, and, on the dry basis, shall contain not less than

(a) 45 per cent ginger starch,

(b) 13·3 per cent cold water extractive as determined by the official method[1], and

(c) 2 per cent ash soluble in water,

and may contain not more than

(d) 9 per cent crude fibre,

(e) 1 per cent calcium, calculated as CaO,

(f) 7·5 per cent total ash, and

(g) 2 per cent ash insoluble in hydrochloric acid.

B.07.003. Jamaica Ginger, whole or ground, shall be ginger grown in Jamaica, and shall conform to the standard provided in B.07.002 except that it shall contain, on the dry basis, not less than 16·6 per cent cold water extractive as determined by the official method.[1]

B.07.004. Limed Ginger (Bleached Ginger), whole or ground, shall be ginger coated with calcium carbonate and shall conform to the standard provided in B.07.002 except that it may contain not more than

(a) 2 per cent calcium, calculated as CaO, and

(b) 11 per cent total ash.

B.07.005. Mustard (Mustard Flour, Ground Mustard) shall be the powder made from mustard seed with the hulls largely removed, with or without the removal of a portion of the fixed oil, and may contain

(a) not more than 1·5 per cent starch,

(b) not more than 7·25 per cent total ash, on the oil-free basis,

and shall yield

(c) not less than 0·40 per cent volatile mustard oil as determined by the official method[1].

B.07.006. Allspice (Pimento), whole or ground, shall be the dried, nearly ripe fruit of the pimento tree, and shall contain not less than 8 per cent quercitannic acid, calculated from the total oxygen absorbed by the aqueous extract, and may contain not more than

(a) 25 per cent crude fibre,

(b) 6 per cent total ash, and

(c) 0·4 per cent ash insoluble in hydrochloric acid.

B.07.007. Cinnamon (Cassia), whole or ground, shall be the dried bark of cultivated varieties of *Cinnamomum zeylanicum* Nees, or *C. cassia* L., from which the outer layers may or may not have been removed, and may contain not more than

(a) 5 per cent ash, and

(b) 2 per cent ash insoluble in hydrochloric acid.

[1] See A.01.010 (*h*)

B.07.008. Ceylon Cinnamon, whole or ground, shall be cinnamon obtained exclusively from *Cinnamomum zeylanicum* Nees.

B.07.009. Mace, whole or ground, shall be the dried arillus of *Myristica fragrans* Houttyn, and may contain not more than

(a) 7 per cent crude fibre,

(b) 3 per cent total ash, and

(c) 0·5 per cent ash insoluble in hydrochloric acid,

and the non-volatile ethyl ether extract, obtained after extraction of mace with petroleum ether, shall not exceed 5 per cent and the sum of the non-volatile extracts with petroleum ether and ethyl ether shall not exceed 33 per cent.

B.07.010. Nutmeg, whole or ground, shall be the dried seed of *Myristica fragrans* Houttyn with or without a thin coating of lime, and shall contain not less than 25 per cent non-volatile ether extract, and may contain not more than

(a) 5 per cent total ash, and

(b) 0·5 per cent ash insoluble in hydrochloric acid.

B.07.011. Black Pepper (Peppercorn), whole or ground, shall be the dried, immature berry of *Piper nigrum* L., and shall contain not less than

(a) 6 per cent non-volatile ether extract, and

(b) 30 per cent pepper starch,

and may contain not more than

(c) 6 per cent total ash, and

(d) 0·9 per cent ash insoluble in hydrochloric acid.

B.07.012. Ground black pepper shall contain all the parts of the berry in their normal proportions.

B.07.013. White Pepper, whole or ground, shall be the dried, mature berry of *Piper nigrum* L., from which the outer coating, or the outer and inner coatings are removed, and shall contain not less than

(a) 7 per cent non-volatile ether extract, and

(b) 52 per cent pepper starch,

and may contain not more than

(c) 5 per cent crude fibre,

(d) 2·2 per cent total ash, and

(e) 0·3 per cent ash insoluble in hydrochloric acid.

B.07.014. Cayenne Pepper (Cayenne), whole or ground, shall be the dried, ripe fruit of *Capsicum frutescens* L., *Capsicum baccatum* L., or other small-fruited species of *Capsicum*, and may contain not more than

(a) 1·5 per cent starch,

(b) 28 per cent crude fibre,

(c) 8 per cent total ash, and

(d) 1·25 per cent ash insoluble in hydrochloric acid,

and shall contain not less than 15 per cent non-volatile ether extract.

B.07.015. Paprika, whole or ground, shall be the dried, ripe fruit of *Capsicum annuum* L., and may contain not more than

(a) 18 per cent non-volatile ether extract,

(b) 23 per cent crude fibre,

(c) 8·5 per cent total ash, and

(d) 1 per cent ash insoluble in hydrochloric acid,

and the iodine number (Hanus) of the extracted oil shall be not less than 125 and not more than 136.

B.07.016. Turmeric, whole or ground, shall be the dried rhizome of *Curcuma longa* L.

B.07.017. Sage, whole or ground, shall be the dried leaves of the sage plant, and may contain not more than 12 per cent stems (excluding petioles) and other foreign material.

B.07.018. Thyme, whole or ground, shall be the dried leaves and flowering tops of the thyme plant, and may contain not more than

(a) 12 per cent total ash, and

(b) 4 per cent ash insoluble in hydrochloric acid.

B.07.019. Caraway Seed shall be the dried fruit of the caraway plant, and may contain not more than

(a) 8 per cent total ash, and

(b) 1·5 per cent ash insoluble in hydrochloric acid.

B.07.020. Cardamom Seed shall be the dried seed of cardamom, and may contain not more than

(a) 8 per cent total ash, and

(b) 3 per cent ash insoluble in hydrochloric acid.

B.07.021. Celery Seed shall be the dried fruit of the celery plant, and may contain not more than

(a) 10 per cent total ash, and

(b) 2 per cent ash insoluble in hydrochloric acid.

B.07.022. Coriander Seed shall be the dried fruit of the coriander plant, and may contain not more than

(a) 7 per cent total ash, and

(b) 1·5 per cent ash insoluble in hydrochloric acid.

B.07.023. Dill Seed shall be the dried fruit of the dill plant, and may contain not more than

(a) 10 per cent total ash, and

(b) 3 per cent ash insoluble in hydrochloric acid.

B.07.024. Mustard Seed shall be the seed of *Sinapis alba* (L); *Brassica hirta* Moench; B. *nigra* (L.) Koch; *B. juncea* (L.) Cosson; or seed of species closely related to *B. nigra* and *B. juncea*, and may contain

(a) not more than 1·5 per cent ash insoluble in hydrochloric acid

and on the oil-free basis, and

(b) not more than 7·25 per cent total ash.

B.07.025. Marjoram, whole or ground, shall be the dried leaves with or without a small proportion of the flowering tops of the marjoram plant, and may contain not more than

(a) 10 per cent stems and foreign material,

(b) 16 per cent total ash, and

(c) 4·5 per cent ash insoluble in hydrochloric acid.

B.07.026. Curry Powder shall be any combination of turmeric with spices and seasoning, and may contain not more than 5 per cent salt.

B.07.027. Onion Salt shall be a combination of powdered dehydrated onion and salt, and shall contain not more than 75 per cent salt with or without not more than 2 per cent of an anti-caking agent.

B.07.028. Garlic Salt shall be a combination of powdered dehydrated garlic and salt, and shall contain not more than 75 per cent salt with or without not more than 2 per cent of an anti-caking agent.

B.07.029. Celery Salt shall be a combination of ground celery seed, or ground dehydrated celery, and salt, and shall contain not more than 75 per cent salt.

B.07.030. Celery Pepper shall be a combination of ground celery seed, or ground dehydrated celery, and ground black pepper, and shall contain not more than 70 per cent ground black pepper.

B.07.031. Mayonnaise (Mayonnaise Dressing, Mayonnaise Salad Dressing) shall be a combination of

(a) vegetable oil,

(b) liquid, frozen or dried whole egg, or egg yolk,

(c) vinegar, or lemon juice,

with or without

(d) water,

(e) salt,

(f) sweetening agent,

(g) spice, or other seasoning except turmeric or saffron, or

(h) citric, tartaric, or lactic acid,

and shall contain not less than 65 per cent vegetable oil.

B.07.032. French Dressing shall be a combination of

(a) vegetable oil, and

(b) vinegar, or lemon juice,

with or without

(c) water,

(d) salt,

(e) sweetening agent,

(f) spice, tomato or other seasoning,

(g) emulsifying agent,

(h) liquid, frozen or dried whole egg, or egg yolk, or

(i) citric, tartaric, or lactic acid,

and shall contain not less than 35 per cent vegetable oil.

B.07.033. Salad Dressing shall be a combination of

(a) vegetable oil,

(b) liquid, frozen or dried whole egg, or egg yolk,

(c) vinegar, or lemon juice, and

(d) cereal,

with or without

(e) water,

(f) salt,

(g) sweetening agent,

(h) spice, or other seasoning,

(i) emulsifying agent, or

(j) citric, tartaric, or lactic acid,

and shall contain not less than 35 per cent vegetable oil.

Dairy Products

B.08.001. The foods referred to in this DIVISION are included within the term *dairy product.*

B.08.002. Except as provided in these regulations, a dairy product that contains a fat other than milk fat is adulterated.

Milk

B.08.005. **Milk (Whole Milk)** shall be the normal lacteal secretion obtained from the mammary gland of the cow, genus *Bos*, and shall be free from colostrum.

B.08.006. **Milk Fat (Butter Fat)** shall be the fat of cow's milk, and shall have

(a) a specific gravity of not less than 0·905 at a temperature of 40°C.,

(b) a tocopherol content not greater than 50 micrograms per gram as determined by the official method[1],

(c) a Reichert-Meissl number not less than 24, and

(d) a Polenske number not exceeding 10 per cent of the Reichert-Meissl number and in no case shall the Polenske number exceed 3·5, and

where the tocopherol content is greater than 50 micrograms per gram or the Polenske number exceeds 10 per cent of the Reichert-Meissl number, there shall be deemed to have been an addition to the milk fat of fat other than that of cow's milk.

B.08.007. **Sterilized Milk** shall be milk that has been heated without concentration or appreciable loss of volume to a temperature of at least 100°C. for a length of time sufficient to kill all the organisms present, and shall be delivered to the consumer in hermetically sealed containers, and shall contain not less than

(a) 11·75 per cent milk solids, and

(b) 3·25 per cent milk fat.

B.08.008. No person shall sell[2] sterilized milk unless the label[3] carries the statement "This milk is not a concentrated product, but has only the food value of normal milk".

B.08.009. **Condensed Milk (Sweetened Condensed Milk** shall be milk from which water has been evaporated and to which sugar, or dextrose, or both, have been added, with or without added vitamin D[4], and shall contain not less than

(a) 28 per cent milk solids, and

(b) 8 per cent milk fat.

B.08.010. **Evaporated Milk (Unsweetened Condensed Milk)** shall be milk from which water has been evaporated, with or without

(a) added vitamin D[4] or

(b) disodium phosphate, or sodium citrate, or both, added in a total quantity of not more than 0·1 per cent of the finished product,

and shall contain not less than

(c) 25·5 per cent milk solids, and

(d) 7·8 per cent milk fat.

B.08.011. **Evaporated Skim Milk (Concentrated Skim Milk)** shall be milk that has been concentrated to at least one-half its original volume by the removal of water, and from which any of the milk fat has been removed, with or without added vitamin D.[4]

B.08.012. Notwithstanding B.08.011, evaporated skim milk from which only part of the milk fat has been removed may be designated **Evaporated Partly Skimmed Milk (Concentrated Partly Skimmed Milk)** if the label carries a statement of the per cent milk fat.

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[1] See A.01.010 (*h*).
[2] See page 1.
[3] See page 1, A.01.010 (*s*) (*t*), B.01.005.
[4] See B.08.015.

B.08.013. Milk Powder (Dry Milk, Dry Whole Milk, Powdered Milk, Powdered Whole Milk) shall be dried milk, and shall contain not less than

(a) 95 per cent milk solids, and

(b) 26 per cent milk fat,

with or without added vitamin D.[1]

B.08.014. Skim Milk Powder (Dry Skim Milk, Powdered Skim Milk) shall be dried skim milk and shall contain not less than 95 per cent milk solids, with or without added vitamin D[1].

B.08.015. No person shall sell[2] condensed milk, evaporated milk, evaporated skim milk, milk powder or skim milk powder, in which the vitamin D content has been increased either by irradiation or addition, unless

(a) it contains, when reconstituted to its original moisture content, not less than 300 and not more than 400 International Units of vitamin D per pint,

(b) in the case of addition, the menstruum containing the vitamin D contributes not more than 0·01 per cent fat foreign to milk, and

(c) the label[3] carries the statement "Vitamin D Increased" or "Vitamin D Added" immediately preceding or following the name of the food, without intervening written, printed, or graphic matter.

B.08.016. (naming the flavour) Milk shall be made from

(a) milk, milk powder, skim milk, or skim milk powder,

(b) flavouring preparation, and

(c) sweetening agent,

with or without food colour,[4] stabilizer, or salt, and shall contain not less than 3·0 per cent milk fat.

B.08.017. Chocolate Drink shall be made from

(a) milk, milk powder, skim milk, or skim milk powder,

(b) cocoa, or chocolate, and

(c) sweetening agent,

with or without food colour,[4] flavouring preparation, acid-reducing salts, stabilizer, or salt, and shall contain not less than 2·0 per cent milk fat.

B.08.018. No person shall sell[2] (naming the flavour) milk or chocolate drink that contains more than 50,000 bacteria per cubic centimetre as determined by the official method.[5]

B.08.019. No person shall sell (naming the flavour) milk or chocolate drink unless the label[3] carries a statement of the per cent milk fat.

B.08.020. Malted Milk (Malted Milk Powder) shall be made by combining milk with the liquid separated from a mash of ground barley malt and meal, with or without the addition of salt, sodium bicarbonate or potassium bicarbonate, in such a manner as to secure the full enzyme action of the malt extract, and by removing water, and shall contain

(a) not less than 7·5 per cent milk fat, and

(b) not more than 3·5 per cent moisture.

B.08.021. (naming the flavour) Malted Milk, (naming the flavour) Malted Milk Powder shall be malted milk containing a flavouring preparation.

Cream

B.08.022. Cream shall be the fatty liquid prepared from milk by separating the milk constituents in such a manner as to increase the milk fat content.

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[1] See B.08.015.
[2] See page 1.
[3] See page 1, A.01.010 (*e*) (*i*), B.01.005
[4] See B.06.
[5] See A.01.010 (*h*).

B.08.023. No person shall sell[1] canned cream unless the label[2] carries a statement of the per cent milk fat.

Cheese

B.08.031. Cheese shall be made by coagulating the casein of milk, skim milk, evaporated milk, evaporated skim milk, cream, milk powder, skim milk powder, or a mixture thereof, with or without the addition of cream, milk powder, skim milk powder or small amounts of other ingredients such as ripening ferments, harmless acid-producing bacterial cultures, special mould cultures, salt, seasoning, special flavouring materials, food colour,[3] or Class III preservative.[4]

B.08.032. Notwithstanding B.08.031, the milk used in the manufacture of cheese may be the normal lacteal secretion of the mammary gland of animals other than the cow, genus *Bos*, if

(a) the label[2] carries a statement of the source of the milk, and

(b) such cheese conforms to all requirements for cheese as provided in this DIVISION.

B.08.033. In this DIVISION, when used in relation to cheese, the expression

(a) "pasteurized source" means milk, skim milk, cream, reconstituted milk powder, or reconstituted skim milk powder or a mixture thereof that has been pasteurized by being held at a temperature of not less than 143°F. for a period of not less than 30 minutes, or for a time and a temperature that is equivalent thereto in phosphatase destruction as determined by the official method,[5]

(b) "stored" means to have kept, held or stored, cheese at a temperature of 35°F. or more for a period of 60 days or more from the date of the beginning of the manufacturing process, and

(c) "whole cheese" means a cheese that is of the original size and shape as manufactured.

B.08.034. No person shall sell[1] any cheese, except Cheddar cheese weighing 10 pounds or more, unless the label[2] carries a statement of the variety or kind of cheese.

B.08.035. **Cheddar Cheese (Canadian Cheddar Cheese)** shall be cheese made by the Cheddar process from matted and milled curd obtained from milk, to which no skim milk has been added or from which no milk fat has been removed, by the action of rennet or other coagulating agent, with or without the addition of not more than 2 per cent bacterial culture and shall contain on the dry basis, not less than 48 per cent milk fat.

B.08.036. The varieties or kinds of cheese listed in the following table shall contain, on the dry basis, not less than the percentage of milk fat required in the table for that variety or kind of cheese:

Variety or Kind of Cheese	Minimum Fat Content on the Dry Basis
	Per cent
PART I	
Blue, Brick, Cheddar, Colby, Danablu, Gorgonzola, Gouda, Granular, Limburger, Mycella, Roquefort and Washed Curd Cheddar.....	48
PART II	
Fynbo, Havarti, Maribo and Samsoe.....	45
Emmenthaler, Gruyere and Swiss.....	43
Edam and Molbo.....	40
Parmesan and Romano.....	32

[1] See page 1.
[2] See page 1, A.01.010 (e) (f), B.01.005.
[3] See B.06.
[4] See B.16.011.
[5] See A.01.010 (h).

B.08.037. Skim Milk Cheese shall be cheese, other than cottage cheese, that contains on the dry basis not more than 15 per cent milk fat.

B.08.038. Cream Cheese shall be cheese made from cream or from milk to which cream has been added, with or without further processing and may contain not more than 0·5 per cent vegetable gum, gelatin or algin, and shall contain

(a) not more than 55 per cent moisture, and

(b) on the dry basis not less than 65 per cent milk fat.

B.08.039. Cream Cheese with (naming the seasoning, relish, condiment or other cheese) shall be cheese made from cream or from milk to which cream has been added with the addition of seasonings, relishes, condiments or other cheese, with or without further processing and may contain not more than 0·5 per cent vegetable gum, gelatin or algin, and shall contain

(a) not more than 60 per cent moisture, and

(b) on the dry basis not less than 50 per cent milk fat.

B.08.040. Process Cheese (Emulsified Cheese, Process Cheese Spread) shall be the food produced by comminuting or mixing one or more lots of cheese into a homogeneous mass with the aid of emulsifying agents, and sufficient degree of heat to bring about pasteurization in the manner described in B.08.033 *(a)*, with or without the addition of water, solids derived from milk, food colour,[1] seasoning, relishes, condiments, or Class III preservative,[2] and the finished product shall contain if manufactured from

(a) a cream cheese base and without the use of seasoning, relishes or condiments,
  (i) not more than 55 per cent moisture, and
  (ii) on the dry basis not less than 65 per cent milk fat, or

(b) a cream cheese base with the use of seasoning, relishes or condiments,
  (i) not more than 60 per cent moisture, and
  (ii) on the dry basis not less than 50 per cent milk fat, or

(c) any cheese named in PART I of the table in B.08.036,
  (i) not more than 43 per cent moisture, and
  (ii) on the dry basis not less than 48 per cent milk fat, or

(d) any other cheese base,
  (i) not more than 43 per cent moisture, and
  (ii) on the dry basis not less than 45 per cent milk fat.

B.08.041. Skim Milk Process Cheese shall conform to the standard for process cheese except that it shall contain not more than

(a) 55 per cent moisture, and

(b) on the dry basis, 15 per cent milk fat.

B.08.042. No manufacturer shall sell[3] whole cheese that is not made from a pasteurized source unless the date of the beginning of the manufacturing process is

(a) marked or branded thereon within three days thereof or

(b) marked on the label at the time of packaging, if the cheese is such that, because of its texture, consistency, or physical structure, such date cannot be effectively branded or marked on the cheese.

B.08.043. No manufacturer shall sell[3] any cheese that is not made from a pasteurized source if it has been cut into smaller portions, unless

(a) it has been duly stored or

(b) each portion of cut cheese is marked, branded or labelled with the date of the beginning of the manufacturing process.

B.08.044. No person shall sell[3] cheese that is not made from a pasteurized source unless it has been stored.

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[1] See B.06.
[2] See B.16.011.
[3] See page 1.

B.08.046. Notwithstanding B.08.044, cheese that has not been manufactured from a pasteurized source and has not been stored but is marked or branded with the date of the beginning of the manufacturing process, may be sold to

(a) a wholesaler,

(b) a jobber, or

(c) in quantities of not less than 900 pounds, to a retailer.

B.08.046. No person shall sell[1] any whole cheese that has not been made from a pasteurized source unless there is stamped thereon the date of the beginning of the manufacturing process.

B.08.047. Every manufacturer, wholesaler, or jobber who sells cheese not made from a pasteurized source and which has not been stored shall keep a record of

(a) the registered number of the cheese factory,

(b) the date of manufacture of the cheese,

(c) the vat number or vat numbers,

(d) the name and address of the person to whom the cheese is sold, and

(e) the weight sold from each vat,

for each lot of cheese sold.

B.08.048. The provisions of B.08.044 do not apply to cheese used as an ingredient in any food that is manufactured or processed so as to pasteurize such cheese in the manner described in B.08.033 *(a)*.

B.08.049. **Whey** shall be the product remaining after the fat and casein have been removed from milk in the process of making cheese.

B.08.050. **Bacterial Culture** shall be the coagulum made by the growth of harmless acid-producing bacteria in milk, reconstituted milk powder or reconstituted skim milk powder.

Butter

B.08.051. **Butter** shall be the food prepared by gathering the milk fat of milk or cream into a mass that may also contain a portion of the other milk constituents not separated in good manufacturing practice, with or without salt or food colour,[2] and shall contain

(a) not less than 80 per cent milk fat, and

(b) not more than 16 per cent moisture.

B.08.052. **Whey Butter** shall be butter made from milk fat that has been recovered from whey.

Ice Cream

B.08.061. **Ice Cream Mix** shall be the unfrozen pasteurized combination of cream, milk, or other milk products, sweetened with sugar, invert sugar, honey or a combination of not less than 75 per cent sugar or invert sugar and not more than 25 per cent dextrose or glucose, with or without

(a) egg,

(b) flavouring preparation,

(c) cocoa or chocolate syrup,

(d) food colour,[2]

(e) acid-reducing salts, or

(f) not more than 0·5 per cent of the finished product of stabilizer,

and shall contain not less than

(g) 36 per cent solids, and

(h) 10 per cent milk fat.

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[1] See page 1.
[2] See B.01.008. B.06.

B.08.062. **Ice Cream** shall be the frozen food made from ice cream mix by freezing, with or without the addition of cocoa or chocolate syrup, fruit, nuts, or confections, and shall contain not less than

(a) 36 per cent solids,

(b) 10 per cent milk fat,

(c) 1·8 pounds of solids per gallon of which amount not less than 0·50 pound shall be milk fat, and

(d) not more than 0·5 per cent stabilizer,

and shall not contain more than 100,000 bacteria per gram as determined by the official method.[1]

Sherbet

B.08.063. **Sherbet** shall be the frozen food other than ice cream made from a milk product, with or without

(a) water,

(b) sweetening agent,

(c) fruit, or fruit juice,

(d) citric, or tartaric acid,

(e) flavouring preparation,

(f) food colour,[2] or

(g) not more than 0·75 per cent of the finished product of stabilizer,

and shall contain

(h) not more than 5 per cent milk solids, including milk fat, and

(i) not less than 0·35 per cent acid determined by titration and expressed as lactic acid.

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[1] See A.01.010 (*h*).
[2] See B.01.008, B.06.

Fats and Oils

B.09.001. Vegetable fats and oils shall be obtained entirely from the botanical source after which they are named, and shall be prepared or processed so as to be dry and sweet in flavour and odour.

B.09.002. Animal fats and oils shall be obtained entirely from animals healthy at the time of slaughter, and shall be prepared or processed so as to be dry and sweet in flavour and odour.

B.09.003. Olive Oil (Sweet Oil) shall be the oil of the fruit of the olive tree, and shall have
- *(a)* a specific gravity (20°C./20°C.) of not less than 0·912 and not more than 0·918,
- *(b)* a refractive index (20°C.) of not less than 1·468 and not more than 1·470,
- *(c)* a Maumené number of not less than 42 and not more than 52,
- *(d)* an iodine value (Hanus) of not less than 77 and not more than 94,
- *(e)* a saponification value of not less than 185 and not more than 195, and
- *(f)* an acid value of not more than 7.

B.09.004. Cotton Seed Oil shall be the oil of the seeds of the cotton plant, and shall have
- *(a)* a specific gravity (20°C./20°C.) of not less than 0·919 and not more than 0·928,
- *(b)* a refractive index (20°C.) of not less than 1·472 and not more than 1·474, and
- *(c)* an iodine value (Hanus) of not less than 100 and not more than 116.

B.09.005. Cacao Butter (Cocoa Butter) shall be the fat from sound cacao beans,[1] obtained either before or after roasting, and shall have
- *(a)* a refractive index (40°C.) of not less than 1·453 and not more than 1·458,
- *(b)* a saponification value of not less than 188 and not more than 202,
- *(c)* an iodine value (Hanus) of not less than 32 and not more than 41, and
- *(d)* an acid value of not more than 5.

B.09.006. Corn Oil (Maize Oil) shall be the oil of the germ of Indian corn, and shall have
- *(a)* a specific gravity (20°C./20°C.) of not less than 0·918 and not more than 0·924,
- *(b)* a refractive index (20°C.) of not less than 1·473 and not more than 1·475,
- *(c)* a saponification value of not less than 188 and not more than 193, and
- *(d)* an iodine value (Hanus) of not less than 111 and not more than 130.

B.09.007. Peanut Oil (Arachis Oil) shall be the oil of the peanut, and shall have
- *(a)* a specific gravity (20°C./20°C.) of not less than 0·913 and not more than 0·920,
- *(b)* a refractive index (20°C.) of not less than 1·468 and not more than 1·472,
- *(c)* a saponification value of not less than 185 and not more than 196, and
- *(d)* an iodine value (Hanus) of not less than 83 and not more than 100.

B.09.008. Soy Bean Oil (Soja Oil, Soya Oil) shall be the oil of the seeds of the soy bean plant, and shall have
- *(a)* a specific gravity (20°C./20°C.) of not less than 0·921 and not more than 0·925, and
- *(b)* a refractive index (20°C.) of not less than 1·472 and not more than 1·476.

B.09.009. Sunflower Seed Oil shall be the oil of the seeds of the sunflower plant, and shall have
- *(a)* a specific gravity (20°C./20°C.) of not less than 0·918 and not more than 0·923,
- *(b)* a refractive index (20°C.) of not less than 1·474 and not more than 1·477,
- *(c)* an iodine value (Hanus) of not less than 125 and not more than 141, and
- *(d)* a saponification value of not less than 185 and not more than 195.

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[1] See B.04.002

B.09.010. No person shall sell any oil as salad oil or table oil unless the label[1] of such oil carries the common name of each oil contained therein arranged in descending order of proportionate content in characters of identical size and type with those used for the word "salad" or the word "table".

B.09.011. Shortening, other than butter or lard, shall be the plastic food prepared from fats, oils, or a combination of fats and oils, which may be processed by hydrogenation, with or without

(a) Class IV preservative,[2]

(b) monoglycerides or a combination of monoglycerides and diglycerides, the weight of the monoglycerides being not more than 10 per cent and the total weight of the monoglycerides and diglycerides being not more than 20 per cent of the weight of the shortening,

and may contain not more than 1 per cent of substances other than monoglycerides, diglycerides, fatty acids and fat.

B.09.012. Monoglycerides, Monoglycerides and Diglycerides shall be monoglycerides or monoglycerides and diglycerides of fat-forming fatty acids (except lauric), and may contain

(a) not more than 0·02 per cent glycine,

(b) not more than 0·02 per cent phosphoric acid,

(c) not more than 2·5 per cent glycerol, and

(d) Class IV preservative.[2]

B.09.013. Lard shall be the rendered fat from hogs, with or without Class IV preservative,[2] and may not contain more than 1 per cent of substances other than fatty acids and fat.

B.09.014. Leaf Lard shall be lard that has been rendered at a moderately high temperature from the internal fat of the abdomen of the hog, excluding that adhering to the intestines, and shall have an iodine value (Hanus) of not more than 65.

B.09.015. Suet shall be fat taken from the region of the kidney or loin or caul fat of a beef carcass.

B.09.016. No person shall sell[3] suet in comminuted form that contains more than 3 per cent cereal or more than 1 per cent salt.

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[1] See page 1, A.01.010 (*e*) (*f*), B.01.005.
[2] See B.16.013.
[3] See page 1.

Flavouring Preparations

B.10.001. Notwithstanding B.01.003 *(a)* (iv), no label declaration is required for the presence of added artificial or imitation flavouring preparation in bakery products, confectionery, ice cream, sherbet, liqueurs and alcoholic cordials and soft drinks.

B.10.002. A flavouring preparation containing added coumarin or an extract of tonka beans, the seed of *Dipteryx odorata* Willd. or *Dipteryx oppositifolia* Willd., is adulterated.

B.10.003. **(naming the flavour) Extract,** or **(naming the flavour) Essence** shall be a solution in ethyl alcohol, glycerol, propylene glycol or any combination of these, with or without added water, sweetening agent, food colour,[1] Class II preservative[2] or Class IV preservative,[3] of sapid or odorous principles, or both, derived from the plant after which the flavouring extract or essence is named.

B.10.004. **Artificial (naming the flavour) Extract, Artificial (naming the flavour) Essence, Imitation (naming the flavour) Extract, Imitation (naming the flavour) Essence** shall be a flavouring extract or essence except that the flavouring principles shall be derived in whole, or in part, from sources other than the aromatic plant after which it is named and the flavouring strength of such artificial or imitation extract or essence shall be not less than that of the extract or essence if such extract or essence is defined in these regulations.

B.10.005. **(naming the flavour) Flavour** shall be a preparation, other than a flavouring preparation described in B.10.003, of sapid or odorous principles, or both, derived from the aromatic plant after which the flavour is named, with or without sweetening agent, food colour[1], Class II preservative[2], Class IV preservative[3], or emulsifying agent and no liquid shall be added to such flavour other than water, ethyl alcohol, glycerol, propylene glycol, or edible vegetable oil.

B.10.006. **Artificial (naming the flavour) Flavour, Imitation (naming the flavour) Flavour** shall be a flavour except that the flavouring principles may be derived in whole or in part from sources other than the aromatic plant after which it is named and the flavouring strength of such artificial or imitation flavour shall be not less than that of the flavour if such flavour is defined in these regulations.

B.10.007. Notwithstanding B.10.003 and B.10.005, a **(naming the fruit) Extract Naturally Fortified, (naming the fruit) Essence Naturally Fortified, (naming the fruit) Flavour Naturally Fortified** shall be an extract, essence, or flavour derived from the named fruit to which other natural extractives have been added and 51 per cent of the flavouring strength shall be derived from the named fruit.

B.10.008. On any label[4] of or in any advertisement for an artificial or imitation flavouring preparation the word "artificial", or "imitation", shall be an integral part of the name of such flavouring preparation, and in identical type, and identically displayed, with such name.

B.10.009. **Almond Essence, Almond Extract, Almond Flavour** shall contain not less than 1 per cent by volume of the hydrocyanic acid-free volatile oil obtained from the kernels of the bitter almond, apricot, or peach.

B.10.010. **Anise Essence, Anise Extract, Anise Flavour** shall be prepared from natural or terpeneless oil of anise and shall correspond in flavouring strength to an alcoholic solution containing not less than 3 per cent by volume of oil of anise, the volatile oil obtained from the fruit of *Pimpinella anisum* L. or *Illicium verum* Hook.

B.10.011. **Celery Seed Essence, Celery Seed Extract, Celery Seed Flavour** shall be prepared from celery seed, or oil of celery seed, or terpeneless oil of celery seed and shall correspond in flavouring strength to an alcoholic solution containing not less than 0·3 per cent by volume of oil of celery seed.

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[1] See B.06.
[2] See B.16.007.
[3] See B.16.013.
[4] See page 1, A.01.010 (*e*) (*i*), B.01.005.

B.10.012. Cassia Essence, Cassia Extract, Cassia Cinnamon Essence, Cassia Cinnamon Extract, Cassia Flavour, Cassia Cinnamon Flavour shall be prepared from natural or terpeneless oil, obtained from leaves and twigs of *Cinnamomum cassia* L., containing not less than 80 per cent cinnamic aldehyde and shall correspond in flavouring strength to an alcoholic solution containing not less than 2 per cent by volume of oil of cassia cinnamon.

B.10.013. Ceylon Cinnamon Essence, Ceylon Cinnamon Extract, Ceylon Cinnamon Flavour shall contain not less than 2 per cent by volume of oil of Ceylon cinnamon, the volatile oil obtained from the bark of *Cinnamomum zeylanicum* Nees, containing

(a) not less than 65 per cent cinnamic aldehyde, and

(b) not more than 10 per cent eugenol.

B.10.014. Clove Essence, Clove Extract, Clove Flavour shall contain not less than 2 per cent by volume of oil of clove, the volatile oil obtained from clove buds.

B.10.015. Ginger Essence, Ginger Extract, Ginger Flavour shall contain in 100 millilitres the alcohol-soluble matter from not less than 20 grams of ginger.

B.10.016. Lemon Essence, Lemon Extract, Lemon Flavour shall be prepared from natural or terpeneless oil of lemon or from lemon peel and shall contain not less than 0·2 per cent citral derived from oil of lemon.

B.10.017. Nutmeg Essence, Nutmeg Extract, Nutmeg Flavour shall be prepared from natural or terpeneless oil of nutmeg and shall correspond in flavouring strength to an alcoholic solution containing not less than 2 per cent by volume of oil of nutmeg.

B.10.018. Orange Essence, Orange Extract, Orange Flavour shall be prepared from sweet orange peel, oil of sweet orange, or terpeneless oil of sweet orange, and shall correspond in flavouring strength to an alcoholic solution containing 5 per cent by volume of oil of sweet orange, the volatile oil obtained from the fresh peel of *Citrus aurantium* L. that shall have an optical rotation, at a temperature of 25°C., of not less than + 95° using a tube 100 millimetres in length.

B.10.019. Peppermint Essence, Peppermint Extract, Peppermint Flavour shall be prepared from peppermint or oil of peppermint, obtained from the leaves and flowering tops of *Mentha piperita* L. or of *Mentha arvensis* De.C., var. *piperascens* Holmes, and shall correspond in flavouring strength to an alcoholic solution of not less than 3 per cent by volume of oil of peppermint, containing not less than 50 per cent free and combined menthol.

B.10.020. Rose Essence, Rose Extract, Rose Flavour shall contain not less than 0·4 per cent by volume of attar of rose, the volatile oil obtained from the petals of *Rosa damascena* Mill, *R. centifolia* L., or *R. moschata* Herrm.

B.10.021. Savory Essence, Savory Extract, Savory Flavour shall be prepared from savory or oil of savory, and shall contain not less than 0·35 per cent by volume of oil of savory.

B.10.022. Spearmint Essence, Spearmint Extract, Spearmint Flavour shall be prepared from spearmint or from oil of spearmint, obtained from the leaves and flowering tops of *Mentha spicata* L., and shall contain not less than 3 per cent by volume of oil of spearmint.

B.10.023. Sweet Basil Essence, Sweet Basil Extract, Sweet Basil Flavour shall be prepared from sweet basil or from oil of sweet basil, obtained from the leaves and tops of *Ocymum basilicum* L., and shall contain not less than 0·1 per cent by volume of oil of sweet basil.

B.10.024. Sweet Marjoram Essence, Sweet Marjoram Extract, Marjoram Essence, Marjoram Extract, Sweet Marjoram Flavour, Marjoram Flavour shall be prepared from marjoram or from oil of marjoram, and shall contain not less than 1 per cent by volume of oil of marjoram.

B.10.025. Thyme Essence, Thyme Extract, Thyme Flavour shall be prepared from thyme or from oil of thyme, and shall contain not less than 0·2 per cent by volume of oil of thyme.

B.10.026. Vanilla Extract, Vanilla Essence, Vanilla Flavour shall be prepared from the vanilla bean, the dried, cured fruit of *Vanilla planifolia*, Andrews, and shall yield a lead number (Winton) of not less than 0·45 and 100 millilitres shall contain not less than 170 milligrams of vanillin as determined by the official method,[1] and notwithstanding B.10.003 and B.10.005 shall contain no added colour.

B.10.027. Wintergreen Essence, Wintergreen Extract, Wintergreen Flavour shall be prepared from oil of wintergreen, the volatile oil distilled from the leaves of *Gaultheria procumbens* L. or from *Betula lenta* L., and shall contain not less than 3 per cent by volume of oil of wintergreen.

[1] See A.01.010 (*h*).

46, December 28, 1956.
Replaces page 46.

Fruits, Vegetables, and their Products

B.11.001. Canned vegetables shall be prepared by heat-processing properly prepared fresh vegetables, with or without

(a) sugar or dextrose,

(b) salt, or

(c) a conditioner,

and shall be packed in hermetically sealed containers.

B.11.002. Canned vegetables may contain as a conditioner, calcium chloride, calcium citrate, monocalcium phosphate, or calcium sulphate only, in an amount not greater than 0·026 per cent, calculated as calcium, if the presence of such conditioner is declared on the main panel of the label[1].

B.11.003. Tomatoes (Canned Tomatoes) shall be the canned vegetable prepared from ripe tomatoes, and shall contain not less than 50 per cent drained tomato solids as determined by the official method.[2]

B.11.004. Tomato Juice shall be the canned, unconcentrated, pasteurized liquid of whole, ripe tomatoes from which all stems and objectionable portions have been removed, with a portion of the pulp, expressed with or without the application of heat, by any method that does not add water to such liquid, and may contain salt, sugar, or dextrose.

B.11.005. The main panel of the label[1] of tomato juice shall carry a declaration by name of any added salt, sugar, or dextrose.

B.11.006. Tomato Pulp shall be the canned vegetable made from whole, ripe tomatoes or sound tomato trimmings concentrated to yield a product with a specific gravity of not less than 1·050 (20°C./20°C.), with or without the addition of Class II preservative.[3]

B.11.007. Tomato Puree shall be the canned vegetable made from whole, ripe tomatoes, with the skins and seeds removed, concentrated to yield a product with a specific gravity of not less than 1·050 (20°C./20°C.), with or without the addition of Class II preservative.[3]

B.11.008. Tomato Paste shall be the canned vegetable made by evaporating a portion of the water from tomatoes or sound tomato trimmings, with or without

(a) salt,

(b) Class II preservative,[3] or

(c) food colour,[4]

and shall not contain skins or seeds, and shall contain not less than 20 per cent tomato solids as determined by the official method.[2]

B.11.009. Concentrated Tomato Paste shall be tomato paste containing not less than 30 per cent tomato solids as determined by the official method.[2]

B.11.010. Tomato Catsup (Catsup) and variants of the word Catsup, shall be the canned vegetable made from the juice of red-ripe tomatoes or sound tomato trimmings from which skins and seeds have been removed, with the addition of

(a) vinegar,

(b) salt,

(c) seasoning, and

(d) sugar,

and may contain

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[1] See page 1, A.01.010 (*e*) (*f*), B.01.005.
[2] See A.01.010 (*h*).
[3] See B.16.007.
[4] See B.06.

(e) Class II preservative,[1] and

(f) food colour,[2]

and where tomato trimmings or tomato products made from tomato trimmings are used the main panel of the label[3] shall carry a declaration of the use of such materials.

B.11.011. Tomato juice or vegetable juices containing tomato juice is adulterated if it

(a) shows mould filaments in more than 25 per cent of the microscopic fields or

(b) contains, per millilitre, more than

(i) 50,000,000 bacteria **or**

(ii) 3,900,000 yeasts and spores

when examined by the official method.[4]

B.11.012. Tomato puree, tomato paste, or tomato catsup is adulterated if it

(a) shows mould filaments in more than 50 per cent of the microscopic fields or

(b) contains, per millilitre, more than

(i) 100,000,000 bacteria or

(ii) 7,500,000 yeasts and spores

when examined by the official method.[4]

B.11.013. **Canned Peas** may contain 0·04 per cent calcium hydroxide or 0·01 per cent magnesium hydroxide, provided that the main panel of the label[3] carries the declaration "Alkali Added".

B.11.014. **Beans with Pork (Beans and Pork)** shall be the canned food prepared from dried beans and pork, with or without sauce, seasoning, spices, or sweetening agent, and shall contain not less than 60 per cent drained solids as determined by the official method.[4]

B.11.015. **Beans (Vegetarian Beans)** shall be the canned food prepared from dried beans, with or without sauce, seasoning, spices, or sweetening agent, and shall contain not less than 60 per cent drained solids as determined by the official method.[4]

B.11.016. Pickles and relishes shall be prepared from vegetables or fruits and salt, and may contain

(a) vinegar,

(b) sugar or dextrose,

(c) spices,

(d) seasonings,

(e) food colour,[2] and

(f) Class II preservative.[1]

Fruits

B.11.031. Canned fruits shall be prepared by heat-processing properly prepared fresh fruit, with or without sugar or dextrose, and shall be packed in hermetically sealed containers.

B.11.032. Canned apples shall be canned fruit to which may be added as a conditioner, calcium chloride, calcium citrate, monocalcium phosphate, calcium sulphate, in an amount not greater than 0·026 per cent, calculated as calcium, if the presence of such conditioner is declared on the main panel of the label.[3]

B.11.033. Frozen fruit shall be fruit preserved by freezing, with or without

(a) sugar or dextrose, or

(b) ascorbic acid to prevent discoloration.

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[1] See B.16.007.
[2] See B.06.
[3] See page 1, A.01.010 (*e*) (*i*), B.01.005.
[4] See A.01.010 (*h*).

B.11.034. The main panel of the label[1] of frozen fruit shall carry a declaration by name of any added sugar or dextrose.

B.11.035. The label[1] of frozen fruit containing added ascorbic acid shall carry the statement "Contains ascorbic acid to prevent discoloration".

Fruit Juices

B.11.045. Fruit juice shall be the unfermented liquid expressed from sound, ripe, fresh fruit, with or without

(a) sugar or dextrose, or

(b) Class II preservative.[2]

B.11.046. The main panel of the label[1] of fruit juice shall carry a declaration by name, and in per cent by weight, of any added sugar or dextrose.

B.11.047. Apple Juice shall be the fruit juice obtained from apples, with or without the addition of vitamin C, and shall have a specific gravity of not less than 1·041 and not more than 1·065 (20°C./20°C.), and shall contain, in 100 millilitres measured at a temperature of 20°C., not less than 0·24 gram and not more than 0·60 gram of ash, of which not less than 50 per cent shall be potassium carbonate.

B.11.048. Grape Juice shall be the fruit juice obtained from grapes, and shall have a specific gravity of not less than 1·040 and not more than 1·124 (20°C./20°C.), and shall contain, in 100 millilitres measured at a temperature of 20°C.,

(a) not less than 0·20 gram and not more than 0·55 gram of ash, and

(b) not less than 0·015 gram and not more than 0·070 gram of phosphoric acid calculated as P_2O_5.

B.11.049. Carbonated (naming the fruit) Juice, Sparkling (naming the fruit) Juice shall be the named fruit juice that is impregnated with carbon dioxide under pressure.

B.11.050. Grapefruit Juice shall be the fruit juice obtained from grapefruit, and shall contain, in 100 millilitres measured at a temperature of 20°C.,

(a) not less than 9·5 grams of soluble solids, and

(b) not less than 1·0 gram and not more than 2·2 grams of acid calculated as anhydrous citric acid,

as determined by the official method.[3]

B.11.051. Lemon Juice shall be the fruit juice obtained from lemons, and shall contain, in 100 millilitres measured at a temperature of 20°C., not less than

(a) 8·0 grams of soluble solids, and

(b) 5·0 grams of acid calculated as anhydrous citric acid,

as determined by the official method.[3]

B.11.052. Lime Juice (Lime Fruit Juice) shall be the fruit juice obtained from limes, and shall have a specific gravity of not less than 1·030 and not more than 1·040 (20°C./20°C.), and shall contain, in 100 millilitres measured at a temperature of 20°C., not less than

(a) 8·0 grams of soluble solids, and

(b) 6·4 grams of acid calculated as anhydrous citric acid,

as determined by the official method,[3] and its optical rotation, determined at a temperature of 20°C., using a tube 200 millimetres in length, shall lie between + 0·5 and - 1·5 degrees Ventzke.

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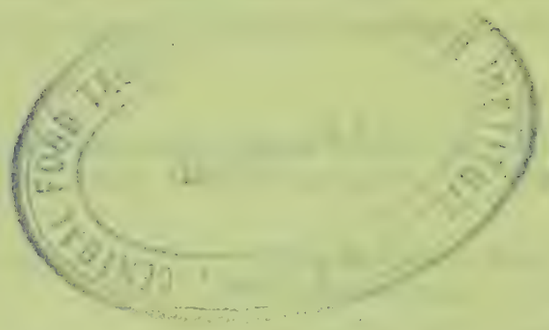
[1] See page 1, A.01.010 (*e*) (*i*), B.01.005.
[2] See B.16.007.
[3] See A.01.010 (*k*).



B.11.053. Orange Juice shall be the fruit juice obtained from oranges, and shall contain, in 100 millilitres measured at a temperature of 20°C.,

(a) not less than 10 grams of soluble solids,

(b) not less than 0·5 gram and not more than 1·9 grams of acid calculated as anhydrous citric acid, and

(c) not less than 8·0 grams of soluble solids to each gram of acid calculated as anhydrous citric acid,

as determined by the official method.[1]

B.11.054. Concentrated fruit juice shall be fruit juice which has been concentrated to at least one-half its original volume by the removal of water, with or without added vitamin C or food colour.[2]

Jams

B.11.065. In this DIVISION an acid ingredient means

(a) citric, malic, or tartaric acid,

(b) lemon or lime juice, or

(c) cider vinegar.

B.11.066. (naming the fruit) Jam shall be made by processing fruit, fruit pulp, or canned fruit, by boiling to a suitable consistency with water and sugar, invert sugar syrup, or dextrose, and shall contain not less than

(a) 45 per cent of the named fruit, except that where such named fruit is strawberry it shall contain not less than 52 per cent,

(b) as determined by the official method,[1] 2·1 per cent insoluble solids where such named fruit is raspberry, or 1·1 per cent insoluble solids where such named fruit is strawberry, and

(c) 66 per cent water-soluble solids as estimated by the refractometer,

and may contain

(d) that amount of added pectin, pectinous preparation, or acid ingredient which reasonably compensates for any deficiency in the natural pectin content or acidity of the named fruit, or

(e) Class II preservative,[3]

and shall not contain apple or rhubarb.

B11.067. (naming the fruit) Jam with Added Pectin shall be made by processing fruit, fruit pulp, or canned fruit, by boiling to a suitable consistency with water and sugar, invert sugar syrup, dextrose, or a combination consisting of not less than 75 per cent sugar, invert sugar, or dextrose and not more than 25 per cent glucose, and shall contain

(a) not less than 27 per cent of the named fruit, except that where such fruit is strawberry it shall contain not less than 32 per cent,

(b) as determined by the official method,[1] not less than 1·2 per cent insoluble solids where such named fruit is raspberry, or 0·7 per cent insoluble solids where such named fruit is strawberry,

(c) not less than 66 per cent water-soluble solids as estimated by the refractometer, and

(d) pectin or pectinous preparation,

and may contain

(e) that amount of acid ingredient that reasonably compensates for any deficiency in the natural acidity of the named fruit,

(f) food colour,[2] or

(g) Class II preservative,[3]

and shall not contain apple or rhubarb.

B.11.068. Apple (or Rhubarb) and (naming the fruit) Jam shall be made by processing fruit, fruit pulp, or canned fruit, by boiling to a suitable consistency with water and sugar, invert sugar syrup, dextrose, or glucose, and shall contain not less than

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[1] See A.01.010 (k).
[2] See B.06.
[3] See B.16.007.

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(a) 12·5 per cent of the named fruit, except that where such fruit is strawberry it shall contain not less than 15 per cent,

(b) 20 per cent apple or rhubarb pulp, and

(c) 66 per cent water-soluble solids as estimated by the refractometer,

and may contain

(d) pectin or pectinous preparation,

(e) that amount of acid ingredient that reasonably compensates for any deficiency in the natural acidity of the fruit used in its preparation,

(f) food colour,[1] and

(g) Class II preservative,[2]

and if more than 25 per cent of the sweetening agent used is glucose the presence of glucose shall be declared on the label.[3]

B.11.069. A jam for which a standard is provided in B.11.068 that contains added pectin or pectinous preparation shall carry on the label a declaration of the addition of such substance.

Marmalade

B.11.075. (naming the fruit) Marmalade shall be the food of jelly-like consistency made from any combination of peel, pulp, or juice of the named citrus fruit, by boiling with water and sugar, invert sugar syrup, or dextrose, and shall contain

(a) not less than 65 per cent water-soluble solids as estimated by the refractometer,

and may contain

(b) that amount of acid ingredient that reasonably compensates for any deficiency in the natural acidity of the named citrus fruit.

B.11.076. (naming the citrus fruit) Marmalade with Added Pectin shall be the food of jelly-like consistency made from any combination of peel, pulp, or juice of the named citrus fruit, by boiling with water and sugar, invert sugar syrup, or dextrose, or a combination consisting of not less than 75 per cent sugar, invert sugar, or dextrose and not more than 25 per cent glucose, and shall contain

(a) not less than 27 per cent of any combination of peel, pulp, or juice of the named citrus fruit,

(b) not less than 65 per cent water-soluble solids as estimated by the refractometer, and

(c) pectin or pectinous preparation,

and may contain

(d) that amount of acid ingredient that reasonably compensates for any deficiency in the natural acidity of the citrus fruit used in its preparation,

(e) Class II preservative.[2]

B.11.077. Pineapple Marmalade, Fig Marmalade, Ginger Marmalade shall be the food of jelly-like consistency made from the pulp or juice of the named fruit or ginger, by boiling with water and sugar, invert sugar syrup, or dextrose, and shall contain not less than

(a) 45 per cent of the named fruit or ginger, and

(b) 65 per cent water-soluble solids as estimated by the refractometer,

and may contain

(c) that amount of added pectin, pectinous preparation, or acid ingredient that reasonably compensates for any deficiency in the natural pectin content or acidity of the named fruit or ginger.

B.11.078. Pineapple Marmalade with Added Pectin, Fig Marmalade with Added Pectin, Ginger Marmalade with Added Pectin shall be the food of jelly-like consistency made from the pulp or juice of the named fruit or ginger, by boiling with water and sugar, invert sugar syrup, dextrose, or a combination consisting of not less than 75 per cent sugar, invert sugar, or dextrose and not more than 25 per cent glucose, and shall contain

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[1] See B.06.
[2] See B.16.007.
[3] See page 1, A.01.010 (*e*) (*i*), B.01.005.

(a) not less than 2½ per cent of the named fruit or ginger,

(b) not less than 65 per cent water-soluble solids as estimated by the refractometer, and

(c) pectin or pectinous preparation,

and may contain

(d) that amount of acid ingredient that reasonably compensates for any deficiency in the natural acidity of the named fruit or ginger,

(e) food colour,[1] and

(f) Class II preservative.[2]

B.11.079. **(naming the fruit) Preserve (Conserve)** shall be the food made by processing fruit other than apple or rhubarb with sugar, invert sugar syrup, or dextrose, and shall contain not less than

(a) 45 parts by weight of the named fruit to each 55 parts by weight of sugar, invert sugar, or dextrose, and

(b) 60 per cent water-soluble solids as estimated by the refractometer.

Jelly

B.11.085. **(naming the fruit) Jelly** shall be the gelatinous food, free of seeds and pulp, made from the named fruit, the juice of the named fruit or a concentrate of the juice of the named fruit, which has been boiled with water and sugar, invert sugar syrup, or dextrose, and shall contain not less than

(a) 62 per cent water-soluble solids as estimated by the refractometer,

and may contain

(b) that amount of added pectin, pectinous preparation, or acid ingredient that reasonably compensates for any deficiency in the natural pectin content or acidity of the named fruit.

B.11.086. **(naming the fruit) Jelly with Added Pectin** shall be the gelatinous food, free of seeds and pulp, made from the named fruit, the juice of the named fruit or a concentrate of the juice of the named fruit, which has been boiled with water and sugar, invert sugar syrup, dextrose, or a combination consisting of not less than 75 per cent sugar, invert sugar, or dextrose, and not more than 25 per cent glucose, and shall contain

(a) not less than the equivalent of 32 per cent juice of the named fruit,

(b) not less than 62 per cent water-soluble solids as estimated by the refractometer, and

(c) pectin or pectinous preparation,

and may contain

(d) that amount of acid ingredient that reasonably compensates for any deficiency in the natural acidity of the named fruit,

(e) juice of another fruit,

(f) gelling agent,

(g) food colour[1], and

(h) Class II preservative.[2]

B.11.087. Standards provided in these regulations for jam and jelly do not apply to cranberry sauce, jellied cranberry, cranberry jelly, mint jelly, and jellied mint.

Pie Fillers

B.11.091. **Apple Pie Filler** shall be the food prepared from

(a) sound portions of mature apples, peeled, cored, and cut into segments or rings, and

(b) sugar, dextrose, or glucose,

with or without

(c) Class II preservative,[2] or

(d) thickener,

and shall contain not less than 20 per cent water-soluble solids as estimated by the refractometer.

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[1] See B.06.
[2] See B.16.007.

B.11.092. Mince (Mince Meat, Fruit Mince) shall be the food prepared from

(a) fruit or dried fruit,

(b) suet,

(c) salt,

(d) spices, and

(e) sweetening agent,

and may contain

(f) vinegar,

(g) fresh, concentrated, or fermented fruit juice,

(h) spirituous liquor,

(i) nuts,

(j) cooked meat, and

(k) Class II preservative.[1]

Boiled Cider

B.11.100. Boiled Cider shall be the liquid expressed from whole apples, apple cores, apple trimmings, or apple culls, that is concentrated by boiling.

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[1] See B.16.007.

Gelling Agents

B.12.001. Gelatin (Edible Gelatin) shall be the purified food obtained by extraction of such tissues as skin, ligaments and bones of animals and when tested by the official method[1] shall contain not less than 82 per cent ash-free solids, and it may contain not more than

(a) 2·6 per cent ash on the dry basis, and

(b) 500 parts per million of sulphurous acid including salts thereof, calculated as sulphur dioxide

and a 5 per cent w/v solution in warm water shall be free from objectionable taste and offensive odour.

B.12.002. Gelatin shall not show the presence of more than 10,000 bacteria per gram, and coliform bacteria shall not be evident in 0·01 gram.

B.12.003. Agar (Agar-Agar) shall be the dried, purified, mucilaginous food obtained by aqueous extraction of seaweeds of different species of *Gelidium*, and may contain on the dry basis, not more than

(a) 7 per cent total ash, and

(b) 1 per cent ash insoluble in hydrochloric acid,

and shall yield with water a practically colourless and tasteless solution.

B.12.004. Irish Moss Gelose (Carrageen, Carrageenin) shall be the dried, purified, mucilaginous food obtained by aqueous extraction of seaweeds of the species *Chondrus crispus*, and shall yield with water a practically clear, colourless, and tasteless solution.

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[1] See A.01.010 (*k*).

Grain and Bakery Products

B.13.001. Flour, White Flour shall be the food prepared by the grinding and bolting of cleaned, milling grades of wheat, and shall

(a) be free from bran coat and germ to such extent that the percentage of ash therein, calculated on a moisture-free basis, does not exceed 1·20 per cent,

(b) have a moisture content of not more than 15 per cent, and

(c) have been bolted through cloth having openings not larger than those of woven wire cloth designated "149 microns (No. 100)",

and may contain

(d) malted wheat flour,

(e) malted barley flour in an amount not exceeding 0·50 per cent of the weight of the flour,

(f) harmless preparations of enzymes obtained from *Aspergillus oryzae*,

(g) oxides of nitrogen,

(h) chlorine,

(i) chlorine dioxide,

(j) nitrosyl chloride,

(k) benzoyl peroxide mixed with not more than six parts by weight of one or a mixture of two or more of

(i) calcium carbonate,
(ii) calcium sulphate,
(iii) dicalcium phosphate,
(iv) magnesium carbonate,
(v) potassium aluminium sulphate,
(vi) sodium aluminium sulphate,
(vii) starch, and
(viii) tricalcium phosphate,

in an amount not exceeding 100 parts by weight of benzoyl peroxide for each 1 million parts of flour,

(l) potassium bromate in an amount not exceeding 50 parts by weight for each 1 million parts of flour, and

(m) ammonium persulphate in an amount not exceeding 250 parts by weight for each 1 million parts of flour.

B.13.002. Enriched Flour, Enriched White Flour shall be flour to which has been added thiamine, riboflavin, niacin and iron in a harmless carrier and in such amounts that one pound of enriched flour shall contain

(a) not less than 2·0 milligrams and not more than 2·5 milligrams of thiamine,

(b) not less than 1·2 milligrams and not more than 1·5 milligrams of riboflavin,

(c) not less than 16·0 milligrams and not more than 20·0 milligrams of niacin or niacinamide,

(d) not less than 13·0 milligrams and not more than 16·5 milligrams of iron, with or without calcium carbonate or edible bone meal in an amount that will provide in one pound of enriched flour not less than 500 milligrams and not more than 650 milligrams of calcium.

B.13.003. Vitamin B White Flour (Canada Approved) shall be flour that has been milled in such a way as to retain a high proportion of the vitamins naturally occurring in the original wheat berry, and shall

(a) constitute not less than 70 per cent of the wheat from which it is milled, and

(b) be bolted through at least one cloth having openings not larger than those of woven wire cloth designated "149 microns (No. 100)",

and on a moisture-free basis shall contain

(c) in one pound an amount of the vitamin B complex that will contribute not less than 1·2 milligrams of thiamine, and

(d) not more than 0·70 per cent and not less than 0·61 per cent ash.

B.13.004. Enriched Vitamin B White Flour shall be Vitamin B White Flour (Canada Approved) to which has been added thiamine, riboflavin, niacin, and iron in a harmless carrier in amounts equivalent to those required to produce enriched flour.

B.13.005. Whole Wheat Flour, Entire Wheat Flour shall be the food prepared by the grinding and bolting of cleaned, milling grades of wheat from which a part of the outer bran or epidermis layer may have been separated, and shall

(a) contain the natural constituents of the wheat berry to the extent of not less than 95 per cent of the total weight of the wheat from which it is milled,

(b) have an ash content, calculated on a moisture-free basis, of not less than 1·25 per cent and not more than 2·25 per cent,

(c) have a moisture content of not more than 15 per cent, and

(d) have a degree of fineness such that not less than 90 per cent bolts freely through a No. 8 (2380 micron) sieve, and not less than 50 per cent through a No. 20 (840 micron) sieve,

and may contain

(e) malted wheat flour,

(f) malted barley flour in an amount not exceeding 0·50 per cent of the weight of the flour,

(g) harmless preparations of enzymes obtained from *Aspergillus oryzae*,

(h) oxides of nitrogen,

(i) chlorine,

(j) chlorine dioxide,

(k) nitrosyl chloride,

(l) benzoyl peroxide mixed with not more than six parts by weight of one or a mixture of two or more of

(i) calcium carbonate,
(ii) calcium sulphate,
(iii) dicalcium phosphate,
(iv) magnesium carbonate,
(v) potassium aluminium sulphate,
(vi) sodium aluminium sulphate,
(vii) starch, and
(viii) tricalcium phosphate,

in an amount not exceeding 100 parts by weight of benzoyl peroxide for each 1 million parts of flour,

(m) potassium bromate in an amount not exceeding 50 parts for each 1 million parts of flour, and

(n) ammonium persulphate in an amount not exceeding 250 parts for each 1 million parts of flour.

B.13.006. Graham Flour shall be flour to which has been added part of the bran and other constituents of the wheat berry, and shall have an ash content, calculated on a moisture-free basis, of not less than 1·20 per cent and not more than 2·25 per cent.

B.13.007. Gluten Flour shall be made from flour by the removal of part of the starch and shall not contain more than 10 per cent moisture, and shall not contain more than 44 per cent starch, calculated on a moisture-free basis, as determined by the official method.[1]

B.13.008. Crushed Wheat, Coarse Ground Wheat shall be the food prepared by so crushing cleaned wheat that 40 per cent or more passes through a No. 8 (2380 micron) sieve and less than 50 per cent through a No. 20 (840 micron) sieve, the proportions of the natural constituents of such wheat, other than moisture, remaining unaltered, and shall have

(a) an ash content, calculated on a moisture-free basis, of not less than 1·50 per cent and not more than 2·25 per cent, and

(b) a moisture content of not more than 15·5 per cent.

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[1] See A.01.010 (k).

B.13.009. **Cracked Wheat** shall be the food prepared by so cracking or cutting cleaned wheat into angular fragments that not less than 90 per cent passes through a No. 8 (2380 micron) sieve and not more than 20 per cent through a No. 20 (840 micron) sieve, the proportions of the natural constituents of such wheat, other than moisture, remaining unaltered, and shall have

(a) an ash content, calculated on a moisture-free basis, of not less than 1·50 per cent and not more than 2·25 per cent, and

(b) a moisture content of not more than 15·5 per cent.

B.13.010. **Rice** shall be the seed of the rice plant hulled, or hulled and polished, with or without the use of talc and glucose.

B.13.011. **Corn Starch** shall be made from maize, and shall contain not less than 84 per cent starch.

B.13.012. No person shall sell[1] flour, enriched flour, vitamin B white flour (Canada Approved), enriched vitamin B white flour, whole wheat flour or graham flour containing or on which has been used oxides of nitrogen, chlorine, chlorine dioxide, nitrosyl chloride or benzoyl peroxide unless

(a) the quantity of such ingredients added be not more than sufficient for bleaching, or in case such ingredient has an artificial aging effect, not more than sufficient for bleaching and such artificial aging effect, and

(b) the main panel of the label[2] carries the word "Bleached".

B.13.013. No person shall sell flour, enriched flour, vitamin B white flour (Canada Approved), enriched vitamin B white flour, whole wheat flour, or graham flour containing or on which has been used chlorine, chlorine dioxide, nitrosyl chloride, potassium bromate or ammonium persulphate unless the main panel of the label carries the words "Maturing agents added".

B.13.014. For the purpose of this DIVISION moisture, ash and fineness shall be determined by the official method.[3]

Bread

B.13.021. **Bread, White Bread** shall be made by baking a yeast-leavened dough prepared with flour and water, and may contain

(a) salt,

(b) shortening, lard, butter or margarine,

(c) milk or milk product,

(d) whole egg, egg-white, egg-yolk, (fresh, dried, or frozen),

(e) sweetening agent,

(f) malt syrup, malt extract, or malt flour,

(g) inactive dried yeast of the genus *Saccharomyces cerevisiae* in an amount not greater than 2 parts by weight for each 100 parts of flour used,

(h) harmless preparations of enzymes obtained from *Aspergillus oryzae*,

(i) oatmeal, corn flour, potato flour, rice flour, soy bean flour, barley flour, vegetable flours, corn starch, potato starch, wheat starch, any of which may be wholly or partially dextrinized, the total of such additions being not more than 5 parts by weight for each 100 parts of flour used,

(j) other parts of the wheat berry,

(k) lecithin,

(l) monoglycerides and diglycerides of fat-forming fatty acids (except lauric acid), the weight of the monoglycerides being not more than 10 per cent, and the total weight of monoglycerides and diglycerides being not more than 20 per cent of the combined weight of the fat and the monoglycerides and diglycerides added,

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[1] See page 1.
[2] See page 1, A.01.010 (*e*) (*i*), B.01.005.
[3] See A.01.010 (*k*).

(m) ammonium chloride, calcium carbonate, calcium lactate, calcium sulphate, diammonium phosphate, dicalcium phosphate, monoammonium phosphate, potassium iodide, or any combination of these, the total being not more than 0·25 part by weight for each 100 parts of flour used,

(n) monocalcium phosphate in an amount not greater than 0·75 part by weight for each 100 parts of flour used,

(o) potassium bromate, potassium iodate, calcium peroxide, ammonium persulphate, potassium persulphate, or any combination of these, the total being not more than 0·0075 part by weight for each 100 parts of flour used,

(p) vinegar,

(q) Class III preservative,[1] and

(r) food colour[2].

B.13.022. Enriched Bread, Enriched White Bread shall be bread baked from a dough in which enriched flour is the only wheat flour used, and shall contain

(a) not less than 2 parts by weight of skim milk solids for each 100 parts of flour used, and in each pound

(b) not less than 1·1 milligrams and not more than 2·4 milligrams of thiamine,

(c) not less than 0·8 milligram and not more than 1·8 milligrams of riboflavin,

(d) not less than 10·0 milligrams and not more than 15·0 milligrams of niacin or niacinamide, and

(e) not less than 8·0 milligrams and not more than 12·5 milligrams of iron.

B.13.023. Vitamin B White Bread (Canada Approved) shall be bread baked from a dough in which Vitamin B White Flour (Canada Approved) is the only flour used, and shall contain not less than

(a) 4 parts by weight of skim milk solids for each 100 parts of flour used, and

(b) in one pound of the bread an amount of the vitamin B complex that will contribute not less than 0·54 milligram of thiamine.

B.13.024. Enriched Vitamin B White Bread shall be Vitamin B White Bread (Canada Approved) in the making of which enriched vitamin B white flour is the only wheat flour used.

B.13.025. Raisin Bread shall be bread that contains for each 100 parts by weight of flour used not less than 50 parts by weight of seeded or seedless raisins, or raisins and currants of which not less than 35 parts shall be raisins, and may contain spices or peel.

B.13.026. (naming the percentage) Whole Wheat Bread shall be bread with or without the addition of caramel, in the making of which the named percentage of the flour used shall be whole wheat flour and the percentage of whole wheat flour shall be not less than 60 per cent of the total flour used.

B.13.027. Brown Bread shall be bread coloured by the use of whole wheat flour, graham flour, bran, molasses, or caramel.

B.13.028. No person shall sell[3] brown bread unless the main panel of the label[4] carries the statements

(a) "Made from (naming the percentage) per cent whole wheat flour" if whole wheat flour is used, otherwise the statement "Made without whole wheat flour", and

(b) "Coloured with (naming the molasses and/or caramel)" if molasses and/or caramel are used.

B.13.029. Notwithstanding B.13.021, specialty breads may contain

(a) the ingredients listed in B.13.021 *(i)* in an amount greater than 5 per cent, and

(b) fruits, nuts, seeds and special flavouring ingredients not provided for in B.13.021 *(i)*.

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[1] See B.16.011.
[2] See B.01.008, B.06.
[3] See page 1
[4] See page 1, A.01.010 (*s*) (*i*) B.01.005.

B.13.030. Notwithstanding B.01.007, enriched bread, whole wheat bread, or brown bread shall be labelled in accordance with these regulations, or a sign shall be prominently displayed on the premises where the bread is sold that carries the information required to appear on the label[1] of these foods by these regulations.

Alimentary Paste

B.13.051. No person shall sell[2] as containing egg, any alimentary paste such as noodles, macaroni, spaghetti, unless such alimentary paste contains on the dry basis not less than 4 per cent egg-yolk solids derived from whole egg, dried egg, frozen egg, or egg-yolk.

Special Dietary Bakery Products

B.13.061. Special dietary bakery products shall be breads, biscuits, cakes, or similar bakery products that contain not more than one-half as much glycogenic carbohydrates as the normal food of the same class.

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[1] See page 1, A.01.010 (e) (f), B.01.005.
[2] See page 1.

Meat, its Preparation and Products

B.14.001. In this DIVISION

(a) "animal" means any animal used as food, but does not include marine and fresh water animals,

(b) "filler" means

(i) flour or meal prepared from grain or potato, but not from a legume,

(ii) bread, biscuit, or bakery products, but not those containing or made with a legume, and

(iii) milk powder, skim milk powder, buttermilk powder, or whey powder.

B.14.002. Meat shall be the clean, dressed flesh, exclusive of the lips, snouts, and ears, of animals healthy at the time of slaughter, and includes the heart, tongue, diaphragm, œsophagus, and skeletal musculature with attendant tissues.

B.14.003. Meat by-product shall be the clean parts other than meat, but inclusive of the lips, snouts, and ears, derived from animals healthy at the time of slaughter, and includes the tissue residues from the processes whereby edible fats are dry-rendered.

B.14.004. Meat, meat by-products or preparations thereof are adulterated if any of the following substances or class of substances is present therein or has been added thereto,

(a) mucous membranes, any organ or portion of the genital system, black gut, spleens, udders, lungs, or any other organ or portion of an animal that is not commonly sold as an article of food,

(b) preservative, other than Class I preservative,[1]

(c) colour, other than caramel.

B.14.005. Prepared meat or prepared meat by-product shall be meat or meat by-product respectively, whether comminuted or not, to which has been added any other ingredient permitted by these regulations, or which has been preserved, canned, or cooked.

B.14.006. A food that consists wholly or in part of a meat by-product or a prepared meat by-product shall be labelled

(a) with the words "meat by-product" or

(b) with the name of the meat by-product.

B.14.007. **Meat Binder, (naming the meat product) Binder** shall be any combination of filler, salt, sugar, dextrose, glucose, spices and other seasonings except tomato, and

(a) when sold for use in preserved meat and preserved meat by-product may contain potassium nitrate, sodium nitrate, sodium nitrite, sodium ascorbate and ascorbic acid, and

(b) when sold for use in prepared meat or meat by-product in which gelling agent is a permitted ingredient, may contain gelling agent.

B.14.008. The label[2] of a filler, represented for use in meat products either by label or in any advertisement, or of meat binder, shall carry directions for use that, when followed, will produce a food that will comply with the requirements of B.14.030 and B.16.006.

B.14.009. Pumping pickle, cover pickle and dry cure employed in the curing of preserved meat or preserved meat by-product may contain

(a) Class I preservative,[1]

(b) ascorbic acid[3] and sodium ascorbate,

(c) sodium bicarbonate, and

in the pumping pickle for cured pork and beef cuts only

(d) disodium phosphate, sodium hexametaphosphate, sodium tripolyphosphate, tetrasodium pyrophosphate and sodium acid pyrophosphate in an amount, calculated as disodium phosphate, which will result in the finished product containing not more than 0·5 per cent added phosphate.

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[1] See B.16.006.
[2] See page 1, A.01.010 (*e*) (*i*), B.01.005.
[3] See B.16.013 (*d*), — .014.

Meats, Meat By-Products

B.14.015. Hamburg (Hamburg Steak) shall be comminuted beef, and shall contain not more than 30 per cent fat which shall be comprised of the fat normally adherent to the beef used.

B.14.016. No person shall sell[1] horse-meat or horse-meat by-product, or any food containing horse-meat or horse-meat by-product unless

(a) it is labelled as such when offered or exposed for sale, and

(b) when in package form, the main panel of the label[2] carries a declaration of the presence of horse-meat or of horse-meat by-product in type at least as legible and conspicuous as any other type upon such main panel.

Prepared Meats, Prepared Meat By-Products

B.14.030. No person shall sell[1] a prepared meat or prepared meat by-product, except blood pudding, black pudding, and white pudding, that contains more than

(a) that amount of filler, meat binder, or other ingredients, that is represented by 4 per cent reducing sugars, calculated as dextrose, as determined by the official method,[3] or

(b) 60 per cent moisture where such prepared meat or prepared meat by-product contains filler.

B.14.031. Preserved meat or preserved meat by-product shall be cooked or uncooked meat or meat by-product to which has been added Class I preservative[4], and shall be salted, pickled, corned, cured, or smoked.

B.14.032. Sausage (Sausage Meat) shall be comminuted meat, either fresh or preserved, with added salt and spices, whether enclosed in a casing or not, and may contain

(a) animal fat,

(b) filler,

(c) beef tripe,

(d) liver,

(e) fresh blood from neat cattle,

(f) sugar, dextrose, or glucose,

(g) other seasonings except tomato, and

(h) meat binder,

with or without subsequent smoking or cooking.

B.14.033. Potted Meat (Meat Paste, Meat Spread) shall be comminuted and cooked, fresh or preserved meat, with or without filler, meat binder, salt, sugar, dextrose, glucose, spices, other seasonings or gelling agent.

B.14.034. Potted Meat By-product (Meat By-product Paste, Meat By-product Spread) shall be made, wholly or in part, from meat by-products, and shall otherwise conform to the standard prescribed for potted meat.

B.14.035. Meat Loaf (Meat Roll, Meat Lunch, Luncheon Meat) shall be comminuted and cooked, fresh or preserved meat, with or without filler, meat binder, salt, sugar, dextrose, glucose, spices, other seasonings, milk, eggs, or gelling agent, pressed into shape.

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[1] See page 1.
[2] See page 1, A.01.010 (*e*) (*i*), B.01.005.
[3] See A.01.010 (*h*).
[4] See B.16.006.

61, May 30, 1956.
Replaces page 61, March 9, 1955.

B.14.036. Meat By-product Loaf, Meat and Meat By-product Loaf shall be made, wholly or in part, from meat by-products, and shall otherwise conform to the standard prescribed for meat loaf.

B.14.037. Head Cheese shall be the comminuted, cooked, edible parts of swine, or other animals, and shall contain

(a) not less than 50 per cent head meat,

(b) no skin other than that naturally adherent to the pork meat used,

and may be prepared with or without added gelling agent.

B.14.038. Brawn shall be head cheese, except that it need not contain 50 per cent of head meat.

B.14.039. The label[1] of prepared meat or prepared meat by-product, to which gelling agent has been added as permitted by these regulations, shall carry a declaration of the presence of added gelling agent, or the word "jellied" as an integral part of the name of the food.

Meat Derivatives

B.14.061. Edible Bone Meal, Edible Bone Flour shall be the food product prepared by grinding dry, defatted bones, obtained from animals healthy at the time of slaughter, and

(a) shall contain not less than 85 per cent ash,

(b) shall not contain more than 1,000 bacteria per gram, and

(c) *Escherichia coli* shall be absent from 1 gram,

as determined by the official method.[2]

Meat Specialties

B.14.070. Wieners and Beans (Wieners with Beans) shall be the canned food prepared from dried beans and wieners with or without sauce, seasoning, spices or sweetening agent and shall contain not less than 25 per cent wieners, as determined by the official method.[2]

B.14.071. Beans and Wieners (Beans with Wieners) shall be the canned food prepared from dried beans and wieners with or without sauce, seasoning, spices or sweetening agent and shall contain not less than 10 per cent wieners, as determined by the official method.[2]

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[1] See page 1, A.01.010 (*e*) (*i*), B 01.005.
[2] See A.01.010 (*h*).

Poisonous Substances in Food

B.15.001. No person shall sell[1] any food in a container that may yield to its contents any substance that may be injurious to the health of a consumer of the food.

B.15.002. Except as provided in these regulations, a food named in Part I or Part II of the table herein set forth, which contains in or upon it

(a) any or all of the poisonous or harmful substances listed in Part I or Part II of the said table, in amounts not exceeding the quantities stated therein in parts per million (p.p.m.) for that food, as determined by an acceptable method[2], and

(b) no other poisonous or harmful substance

is hereby exempted from the provision of paragraph *(a)* of Section 4 of the Act.

TABLE

Part I

Food	Substance				
	Arsenic p.p.m.	Lead p.p.m.	Copper p.p.m.	Zinc p.p.m.	Fluorine p.p.m.
Citric Acid	1	10	50	50	2
Tartaric Acid	1	10	50	50	2
Cream of Tartar	2	20	50	50	2
Sodium Bicarbonate	2	5	50	50	2
Baking Powder	2	10	50	50	10
Phosphoric Acid	4	5	30	30	20
Calcium Phosphate	4	5	30	30	30
Sodium, Potassium and Ammonium Phosphates	4	5	30	30	20
Sodium and Potassium Nitrates	1	10	50	50	2
Sodium Nitrite	1	20	50	50	2
Aluminium Compounds	3	10	50	50	2
Marine and Fresh Water Animal Products	5	10	100	100	25
Liver	1	2	150	100	2
Fresh Fruits	2	7	50	50	2
Fresh Vegetables	1	2	50	50	2
Gelatin	2	7	30	100	2
Gelling Agents except Gelatin	2	20	50	200	2
Dried Herbs and Spices	5	10	50	50	20
Apple Juice, Cider, Wine and Beer	0·2	0·5	2	5	2
Fruit Juice except Apple Juice	0·1	0·2	2	5	1
Beverages as Consumed and Bottled Water	0·1	0·2	2	5	2
Tea	1	10	150	50	100
Edible Bone Meal	1	10	20	150	650

[1] See page 1.
[2] See A.01.010 (*a*).

63, May 30, 1956.
Replaces page 63

Substance	Chemical name (where applicable)	Tolerance p.p.m.	Foods
Aramite	2-(*p*-tertiary butyl phenoxy) isopropyl, 2-chloroethylsulfite	1	Apples, beans, blueberries, cantaloupe, celery, corn, cucumbers, grapes, grapefruit, lemons, oranges, peaches, pears, plums, prunes, raspberries, soy beans, strawberries, tomatoes, watermelon.
Captan	N-trichloromethylmercapto-4-cyclohexene 1, 2-dicarboximide	20	Cherries, grapes, peaches, strawberries.
		15	Apples, apricots, cantaloupes, cucumbers, eggplants, grapefruit, lemons, limes, mangoes, nectarines, oranges, pears, peppers, pineapples, plums, prunes, pumpkins, quinces, squash, summer squash, tangerines, tomatoes, watermelons.
Malathion	O,O′-dimethyl dithiophosphate of diethyl mercapto succinate	8	Apples, apricots, avocados, beans, beets, Brussels sprouts, celery, cherries, cole crops, cranberries, cucumbers, egg plants, grapes, lettuce, melons, onions, peaches, pears, peas, pecans, peppers, pineapple, plums, potatoes, prunes, rutabagas, small grains, spinach, squash, strawberries, tomatoes.
Parathion	O, O—diethyl— O, *p*-nitrophenylthiophosphate	1	Apples, apricots, beans, beets, blackberries, blueberries, broccoli, Brussels sprouts, cabbages, carrots, cauliflower, celery, cherries, corn, cranberries, cucumbers, currants, eggplants, endive, gooseberries, grapes, hops, kale, kohlrabi, lettuce, loganberries, melons, onions, parsnips, peaches, pears, peas, peppers, plums, pumpkins, quinces, radishes, raspberries, rutabagas, spinach, squash, strawberries, summer squash, swiss chard, tomatoes, turnips.
Stop Mould B	Sodium orthophenyl phenate (as orthophenylphenol)	5	Apples, pears.

63A, July 12, 1956.
Replaces page 63A, May 30, 1956.

Substance	Chemical name (where applicable)	Tolerance p.p.m.	Foods
Ovotran	*p*-chlorophenyl *p*-chlorobenzene sulfonate	3	Apples, peaches, pears, plums, prunes.
		5	Citrus fruits.
Piperonyl Butoxide		20	Barley, buckwheat, corn, pop-corn, rice, rye, wheat.
Pyrethrins		3	Barley, buckwheat, corn, pop-corn, rice, rye, wheat.
Ethylene dibromide		5	Lima beans, strawberries.
		10	Asparagus, cauliflower, corn.
		50	Sweet potatoes.
		75	Carrots, parsnips.
Sulphenone	*p*-chlorophenyl-phenylsulfone	8	Apples, pears, peaches.
Methyl Bromide as inorganic bromide		5	Apples, pears, quince.
		20	Dried fruits (apricots, peaches, prunes, raisins), egg plant, onions, tomatoes.
		30	Beets, rutabagas, turnips.
		50	Barley, beans, black-eyed peas, cocoa. beans corn, grain sorghum, green beans, lima beans, oats, rice, rye, snap beans, wheat.
		75	Potatoes, sweet potatoes.
		200	Almonds, Brazil nuts, bush nuts, butternuts, cashew nuts, chestnuts, cottonseed, filberts, hazelnuts, hickory nuts, peanuts, pecans, walnuts.

Preservatives

B.16.001. No person shall

(a) use as a preservative in or upon food, or

(b) sell[1] as a preservative for food

any substance other than those designated in this DIVISION as Class I, Class II, Class III, or Class IV preservatives.

B.16.002. No person shall sell[1]

(a) benzoic acid, including salts thereof,

(b) sulphurous acid, including salts thereof,

(c) propyl gallate,

(d) butylated hydroxyanisole,

(e) nordihydroguaiaretic acid, or

(f) butylated hydroxytoluene,

for use as a preservative for food, unless the label[2] carries a quantitative statement of the amounts of such preservatives present.

B.16.003. Where any Class II, Class III, or Class IV preservative is sold for use as a preservative for food, the label[2] shall carry adequate directions for use in accordance with the limits prescribed for such preservative in this DIVISION.

B.16.004. Notwithstanding B.01.003 *(a)* (ii), no label declaration is required for the presence of sulphurous acid, including salts thereof, in or upon

(a) glucose,

(b) (naming the source of the glucose) syrup,

(c) confectionery containing glucose,

(d) molasses,

(e) refiners' syrup,

(f) sugar-cane syrup, or

(g) wine.

B.16.005. Notwithstanding B.01.003 *(a)* (ii), no label declaration is required for the presence of Class III preservative, in or upon

(a) bread,

(b) bakery products,

(c) cheese, or

(d) process cheese.

B.16.006. Class I preservatives shall be

(a) alcohol,

(b) ascorbic acid,

(c) dextrose,

(d) glucose,

(e) potassium nitrate,

(f) salt,

(g) sodium ascorbate,

(h) sodium nitrate,

(i) sodium nitrite in fresh fish, preserved fish, and preserved meat only, in an amount not exceeding 200 parts per million of the finished product,

(j) spices,

(k) sugar,

(l) vinegar, and

(m) wood smoke.

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[1] See page 1.
[2] See page 1, A.01.010 *(e)* *(i)*, B.01.005.

B.16.007. Class II preservatives shall be

(a) benzoic acid, including salts thereof,

(b) sulphurous acid, including salts thereof, and

(c) sorbic acid.

B.16.008. No person shall use in or upon a food more than one Class II preservative.

B.16.009. No person shall use in or upon a food, more than

(a) 1,000 parts per million of benzoic acid or

(b) 1,000 parts per million of sorbic acid.

B.16.010. Except as provided in these regulations, no person shall use sulphurous acid, calculated as sulphur dioxide, in amounts greater than

(a) 100 parts per million in beverages as prepared for consumption in accordance with label directions,

(b) 2,500 parts per million in or upon dried fruits and vegetables, or

(c) 500 parts per million in or upon other foods.

B.16.011. Class III preservatives shall be

(a) propionic acid, including salts thereof,

(b) sodium diacetate, and

(c) sorbic acid.

B.16.012. No person shall use in or upon a food, more than

(a) 2,000 parts per million of propionic acid,

(b) 3,000 parts per million of sodium diacetate, or

(c) 1,000 parts per million of sorbic acid.

B.16.013. Class IV preservatives shall be

(a) gum guaiacum,

(b) vegetable oils containing tocopherols,

(c) lecithin,

(d) citric, tartaric, or ascorbic acid,

(e) monoisopropyl citrate,

(f) ascorbyl palmitate,

(g) propyl gallate,

(h) nordihydroguaiaretic acid,

(i) butylated hydroxyanisole (a mixture of 2-tertiarybutyl-4-hydroxyanisole and 3-tertiarybutyl-4-hydroxyanisole), and

(j) butylated hydroxytoluene (3, 5-di-tertiarybutyl-4-hydroxytoluene), (2, 6-di-tertiarybutyl paracresol), or (2, 6-di-tertiarybutyl-4-methyl phenol)

with or without a harmless carrier.

B.16.014. No person shall use in or upon a food, Class IV preservatives, singly or in combination, including the carrier, in an amount greater than 0·2 per cent of the finished product except that a food shall not contain more than

(a) 0·01 per cent propyl gallate,

(b) 0·005 per cent nordihydroguaiaretic acid,

(c) 0·01 per cent butylated hydroxyanisole,

(d) 0·01 per cent butylated hydroxytoluene, and

(e) 0·02 per cent of a combination of not more than three of the Class IV preservatives listed in paragraphs *(a)*, *(b)*, *(c)* and *(d)* of this section.

B.16.015. No person shall use in or upon a food a combination of propyl gallate and nordihydroguaiaretic acid.

Salt

B.17.001. **Salt** shall be crystalline sodium chloride, and may contain not more than

(a) 1·4 per cent calcium sulphate, and

(b) 0·1 per cent other impurities.

B.17.002. **Free-Running Salt** shall be fine-grained salt to which has been added not more than 1 per cent of an anticaking agent.

B.17.003. Notwithstanding the provisions of B.17.002, **Free-Running Flour Salt** shall be fine-grained salt to which has been added not more than 2 per cent of an anticaking agent.

B.17.004. No person shall sell[1] salt or free-running salt for table or general household use unless it contains 0·01 per cent potassium iodide, and the presence of the iodide is declared on the main panel of the label.[2]

[1] See page 1.
[2] See page 1, A.01.010 (*e*) (*i*), B.01.005.

Sweetening Agents

B.18.001. **Sugar** shall be the food chemically known as sucrose, and if sold as granulated, cut-loaf, cube, milled, or powdered sugar, shall contain not less than 99·8 per cent sucrose.

B.18.002. **Icing Sugar** shall be powdered sugar, with or without

(a) added food colour,[1] or

(b) not more than 5 per cent starch.

B.18.003. **Brown Sugar (Yellow Sugar, Golden Sugar)** shall be made by the partial refinement of the juice of the sugar-cane or other sugar-producing plant, and shall not contain more than

(a) 4·5 per cent moisture, and

(b) 3·5 per cent sulphated ash,

and shall contain not less than 90 per cent sugar and invert sugar.

B.18.004. **Molasses** shall be

(a) the mother liquor obtained by evaporating the juice of the sugar-cane until a large proportion of the sugar has been separated by crystallization, or

(b) the syrupy food obtained by evaporation and partial inversion of the juice of the sugar-cane which juice may or may not be clarified with or without the addition of sulphurous acid,[2]

and shall not contain more than

(c) 25 per cent moisture, and

(d) 9 per cent sulphated ash,

and where the sulphated ash content does not exceed 3 per cent it may be called **Table Molasses.**

B.18.005. **Refiners' Syrup, Refiners' Molasses** shall be the residual liquid obtained in the process of refining raw sugar, with or without the addition of sulphurous acid,[2] and shall not contain more than

(a) 25 per cent moisture, and

(b) 12 per cent sulphated ash.

B.18.006. **Sugar-cane Syrup** shall be made by the evaporation of the juice of the sugar-cane, with or without the addition of sulphurous acid,[2] and shall not contain more than

(a) 25 per cent moisture, and

(b) 3 per cent sulphated ash.

Dextrose, Glucose

B.18.015. **Dextrose,** for the purpose of **Part B** of these regulations, shall be the food chemically known as dextrose, and shall not contain more than 10 per cent moisture.

B.18.016. **Glucose** shall be the thick, syrupy, nearly colourless food made by incomplete hydrolysis of starch or of a starch-containing substance, and shall not contain

(a) more than 22 per cent moisture,

(b) more than 1 per cent ash, and

(c) less than 40 per cent reducing sugars, calculated as dextrose on a moisture-free basis,

and may contain sulphurous acid[2].

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[1] See B.01.008, B.06.
[2] See B.16.004.

B.18.017. (naming the source of the glucose) Syrup shall be a combination of glucose with a sweetening agent, with or without the addition of a flavouring preparation, and shall not contain more than

(a) 35 per cent moisture, and

(b) 3 per cent ash,

and may contain sulphurous acid.[1]

Honey

B.18.025. Honey shall be derived entirely from the nectar of flowers and other sweet exudation of plants by the work of bees, and shall not contain more than

(a) 20 per cent moisture,

(b) 8 per cent sucrose, and

(c) 0.25 per cent ash,

and shall contain not less than 60 per cent invert sugar.

[1] See B.16.004.

Vinegar

B.19.001. Vinegar shall be the liquid obtained by the acetous fermentation of an alcoholic liquid, and shall contain not less than 4·1 per cent, or more than 12·3 per cent acetic acid.

B.19.002. If any reference is made by any statement, mark, or device, to the strength of a vinegar on the label of or in any advertisement for a vinegar, the label shall carry a statement of the strength of the vinegar declared in per cent, and the strength of the vinegar shall be calculated in terms of acetic acid.

B.19.003. Wine Vinegar shall be vinegar made from wine, with or without the addition of caramel.[1]

B.19.004. Spirit Vinegar (Alcohol Vinegar, White Vinegar, Grain Vinegar) shall be vinegar made from diluted distilled alcohol.

B.19.005. Malt Vinegar shall be vinegar made from an infusion of malt undistilled prior to acetous fermentation, with or without the addition of other cereals, or caramel, and shall be dextro-rotatory, and shall contain, in 100 millilitres measured at a temperature of 20°C., not less than

(a) 1·8 grams of solids, and

(b) 0·2 gram of ash.

B.19.006. Cider Vinegar (Apple Vinegar) shall be vinegar made from the liquid expressed from whole apples, or apple culls, with or without the addition of caramel.[1]

B.19.007. Blended Vinegar shall be a combination of two or more varieties of vinegar of which spirit vinegar shall contribute not more than 55 per cent of the total acetic acid.

B.19.008. No person shall name any of the varieties of vinegar forming a blended vinegar unless the label[2] of such blended vinegar carries a complete list of all the varieties of vinegar present, in descending order of proportionate content, based on acetic acid.

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[1] See B.01.009.
[2] See page 1, A.01.010 (*e*) (*i*), B.01.005.

69, August 10, 1955.
Replaces page 69.

Tea

B.20.001. Tea shall be the dried leaves and buds of *Thea sinensis* (L.) Sims prepared by the usual trade processes.

B.20.002. Black Tea shall contain, on the dry basis, not less than 30 per cent water-soluble extractive as determined by the official method,[1] and not less than 4 per cent and not more than 7 per cent total ash.

B.20.003. Green Tea shall contain, on the dry basis, not less than 33 per cent water-soluble extractive as determined by the official method,[1] and not less than 4 per cent and not more than 7 per cent total ash.

[1] See A.01.010 (*h*).

Marine and Fresh Water Animal Products

B.21.001. The foods referred to in this DIVISION are included in the term *marine and fresh water animal products.*

B.21.002. In this DIVISION

(a) "marine and fresh water animal" includes
  (i) fish,
  (ii) crustaceans, molluscs, other marine invertebrates, and
  (iii) marine mammals,

(b) "fish" means the clean, dressed, edible portion of fish,

(c) "meat" means the clean, dressed flesh of crustaceans, molluscs, other marine invertebrates, and marine mammals,

(d) "filler" means
  (i) flour or meal prepared from grain or potato, but not from a legume,
  (ii) bread, biscuit, or bakery products, but not those containing or made with a legume, and
  (iii) milk powder, skim milk powder, buttermilk powder, or whey powder.

B.21.003. Marine and fresh water animal products are adulterated if any of the following substances or class of substances is present therein or has been added thereto

(a) mucous membranes, any organ or portion of the genital system, or any organ or portion of a marine or fresh water animal that is not commonly sold as an article of food,

(b) preservative, other than Class I preservative,[1] and

(c) food colour,[2] except in smoked fish, lobster paste and fish roe (caviar).

B.21.004. Prepared fish or prepared meat shall be fish or meat respectively, whether comminuted or not, to which has been added any other ingredient permitted by these regulations, or which has been preserved, canned, or cooked.

B.21.005. **Fish Binder** shall be any combination of filler, salt, sugar, dextrose, glucose, spices and other seasonings, that is used in or upon prepared fish.

B.21.006. No person shall sell[3] filler, represented for use in fish products either by label or in any advertisement or a fish binder, unless the label[4] carries adequate directions for use in accordance with the limits provided in B.21.020.

B.21.007. No person shall sell[3] fish that has in or upon it chlortetracycline if

(a) the amount thereof exceeds 5 parts per million, and

(b) its presence is not declared by name on the main panel of the label.[4]

B.21.008. No person shall sell[3] canned crab meat that has in or upon it citric acid, unless the presence thereof is declared by name on the main panel of the label.[4]

Prepared Fish

B.21.020. No person shall sell prepared fish that contains more than

(a) that amount of filler, fish binder or other ingredients that is represented by 4 per cent reducing sugars, calculated as dextrose, as determined by the official method,[5] and

(b) 70 per cent moisture where such prepared fish contains filler.

B.21.021. Preserved fish shall be cooked or uncooked fish, to which has been added Class I preservative[1] and which shall be salted, pickled, cured or smoked.

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[1] See B.16.006.
[2] See B.06.
[3] See page 1.
[4] See page 1, A.01.010 (a) (i), B.01.005.
[5] See A.01.010 (h).

B.21.022. Fish Sausage (Fish Sausage Meat) shall be comminuted fish, either fresh or preserved, with added salt and spices, and may contain

(a) animal fat,

(b) filler,

(c) seasoning, and

(d) sugar, dextrose, or glucose.

Shucked Oysters

B.21.030. No person shall sell[1] shucked oysters that contain by volume more than 10 per cent fluid separable by draining for five minutes through a No. 10 (1680 micron) sieve.

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[1] See page 1.

Poultry, Poultry Meat, their Preparations and Products

B.22.001. Poultry shall be any bird that is commonly used as food.

B.22.002. Poultry meat shall be the clean, dressed flesh, exclusive of the giblets, of eviscerated poultry, healthy at the time of slaughter.

B.22.003. Poultry meat by-product shall be the clean parts of poultry other than poultry meat commonly used as food and includes the giblets and skin, but excludes the œsophagus, feet, and head.

B.22.004. Giblets shall be the heart, liver, and gizzard of poultry.

B.22.005. Poultry, Poultry Meat, Poultry Meat By-products, and preparations thereof are adulterated if any of the following substances or class of substances is present therein or has been added thereto, namely,

(a) any organ or portion of poultry that is not commonly sold as food,

(b) preservative other than Class I preservative,[1]

(c) colour other than caramel.

B.22.006. Prepared poultry meat or prepared poultry meat by-product shall be poultry meat or poultry meat by-product, whether comminuted or not, to which has been added any other ingredient permitted by these regulations, or which has been preserved, canned, or cooked.

B.22.007. A food that consists wholly or in part of a poultry meat by-product or a prepared poultry meat by-product shall carry on the label[2]

(a) the words "poultry meat by-product" or

(b) the name of the poultry meat by-product.

B.22.008. In this DIVISION filler shall be

(a) flour or meal prepared from grain or potato, but not from a legume,

(b) bread, biscuit, or bakery products, but not those containing or made with a legume, and

(c) milk powder, skim milk powder, butter milk powder, or whey powder.

B.22.009. No person shall sell for consumption as food, poultry to which has been administered any preparation having œstrogenic activity.

Prepared Poultry Meats, Prepared Poultry Meat By-products

B.22.020. No person shall sell[3] a prepared poultry meat or a prepared poultry meat by-product that contains more than

(a) that amount of filler or other ingredient that is represented by 4 per cent reducing sugars, calculated as dextrose, as determined by the official method[4] or

(b) 60 per cent moisture where such prepared poultry meat or prepared poultry meat by-product contains filler.

B.22.021. Preserved poultry meat or preserved poultry meat by-product shall be cooked or uncooked poultry meat or poultry meat by-product, to which has been added Class I preservative,[1] and shall be cured or smoked.

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[1] See B.16.006.
[2] See page 1, A.01.010 (*e*) (*i*), B.01.005.
[3] See page 1.
[4] See A 01.010 (*h*).

B.22.022. Canned poultry shall be prepared from poultry meat, and may contain

(a) those bones or pieces of bones attached to the portion of the poultry meat that is being canned,

(b) broth,

(c) salt,

(d) seasoning,

(e) gelling agent, or

(f) small amounts of fat.

B.22.023. Broth that is used in canned poultry shall be the liquid in which the poultry has been cooked.

B.22.024. Canned poultry containing gelling agent shall carry on the label[1] a declaration of the presence of the added gelling agent or the word "Jellied" as an integral part of the name of the food.

B.22.025. Boneless (naming the poultry) shall be canned poultry from which the bones and skin have been removed, and any liquid added shall be broth having a specific gravity of not less than 1·000 at a temperature of 50°C., and shall contain not less than 50 per cent of the named poultry meat as determined by the official method[2].

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[1] See page 1, A.01.010 (*e*) (*i*), B.01.005.
[2] See A.01.010 (*h*).

DRUGS

Division 1

General

C.01.001. In this **Part**

(a) "antibiotic" means any drug or combination of drugs such as those named in C.01.410 to C.01.592 which is prepared from certain micro-organisms, or which formerly was prepared from micro-organisms but is now made synthetically and which possesses inhibitory action on the growth of other micro-organisms,

(b) "common name" means, with reference to a drug, the name in English or French by which the drug is commonly known,

(c) "expiration date" means any date prescribed by these regulations as the expiration date and after which a drug is not recommended for use,

(d) "internal use" means ingestion by mouth or application for systemic effect to any part of the body in which the drug comes into contact with mucous membrane,

(e) "new drug" means a drug that because of
(i) its method of manufacture,
(ii) its composition,
(iii) its dosage,
(iv) its route of administration, or
(v) the claims made for it

is not generally recognized by experts qualified to evaluate the drug, as safe for the use for which it is proposed or recommended,

(f) "official drug" means any drug
(i) for which a standard is provided in these regulations or
(ii) for which no standard is provided in these regulations but for which a standard is provided in any of the publications mentioned in SCHEDULE B[1] to the Act,

(g) "parenteral use" means administration of a drug by means of a hypodermic syringe, needle or other instrument through or into the skin or mucous membrane,

(h) "per cent" means per cent by weight unless otherwise stated,

(i) "practitioner" means a person authorized by the law of a province of Canada to treat patients with any drug listed or described in SCHEDULE F[2] to the Act,

(j) "prescription" means an order given by a practitioner directing that a stated amount of any drug or mixture of drugs specified therein be dispensed for the person named in the order,

(k) "proper name" means, with reference to a drug, the name in English or French
(i) assigned to the drug in C.01.002,
(ii) that appears in bold-face type for the drug in these regulations,
(iii) specified in the Canadian licence[3] in the case of drugs included in SCHEDULE C[4] or SCHEDULE D[5] to the Act, or
(iv) assigned in any of the publications mentioned in SCHEDULE B[1] to the Act in the case of drugs not included in (i), (ii), or (iii) of this paragraph, and

(l) "teaspoon" means, for the purpose of calculation of dosage, a volume of five cubic centimetres.

C.01.002. Proper names of drugs shall be those shown in the column headed "Proper Names" in the following table:

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[1] See page 9.
[2] See page 10.
[3] See C.03.001 (*b*), C.04.001 (*c*).
[4] See page 9.
[5] See page 10.

TABLE

Proper Names	*Chemical Names and Synonyms*
Acetanilide: Acetanilid	Acetylaminobenzene: Antifebrin: Phenylacetamide
Aminoacetic Acid: Glycocoll	Aminoacetic acid: Glycine
Aminopyrine	1, 5-dimethyl-2-phenyl-4-dimethylamino-3-pyrazolone: Dimethylaminophenazone
Amphetamine	β-aminopropylbenzene
Barbitone: Barbital	5, 5-diethylbarbituric acid: Diethylmalonylurea
Bishydroxycoumarin	3, 3′-methylene-bis (4-hydroxycoumarin): Dicoumarol
Bromisoval	2-monobromoisovalerylurea: Bromisovalum: Bromvaletone
Butabarbital Sodium	Sodium 5-*sec.*-butyl-5-ethylbarbiturate
Butethal	5-ethyl-5-*n*-butyl barbituric acid Butobarbitone
Caffeine	1, 3, 5-trimethyl-2, 6-dioxypurine
Carbromal	α-bromo-α-ethylbutyrylcarbamide
Chloromethapyrilene	N, N-dimethyl-N′-(2-pyridyl)-N′-(5-chloro-2-thenyl)-ethylenediamine: Chlorothen
Cinchocaine	2-butoxy-N-(2-diethylaminoethyl) cinchoninamide: Dibucaine
Cinchophen	2-phenylquinoline-4-carboxylic acid Quinophan
Disulfiram	Tetraethylthiuram disuphide
Hexobarbitone: Hexobarbital	1, 5-dimethyl-5Δ^1-cyclohexenyl barbituric acid
Iproniazid	1-isonicotinyl-2-isopropylhydrazide
Isoniazid	Isonicotinyl hydrazide
Mephenesin	3-*o*-toloxy-1, 2-propanediol
Mepyramine	N, N-dimethyl-N′-(*p*-methoxybenzyl)-N′-(2-pyridyl)-ethylenediamine: Pyrilamine
Mersalyl	Sodium [*o*(hydroxymercurimethoxy-propylcarbamyl) phenoxyl] acetate
Methadone	6-dimethylamino-4, 4-diphenyl-3-heptanone
Methamphetamine	d-N, α-dimethylphenethylamine: d-desoxyephedrine
Paramethadione	3, 5-dimethyl-5-ethyl-2, 4-oxazolidinedione
Phenacetin	*p*-acetphenetidin: Acetphenetidin: Acetophenetidin: *p*-ethoxyacetanilid
Phenobarbitone: Phenobarbital	5-phenyl-5-ethylbarbituric acid: Phenylethylmalonylurea
Phenylindanedione	2-phenylindane-1, 3-dione
Pholedrine	*p*-(4-hydroxyphenyl)-isopropylmethylamine
Procaine	*p*-aminobenzoyldiethylaminœthanol: Ethocaine
Soluble Barbitone: Barbitone Sodium: Soluble Barbital: Barbital Sodium	Sodium 5, 5-diethylbarbiturate: Sodium diethylmalonylurea
Soluble Phenobarbitone: Phenobarbitone Sodium: Phenobarbital Sodium: Soluble Phenobarbital	Sodium 5-phenyl-5-ethylbarbiturate: Sodium phenylethylmalonylurea

75, September 6, 1956.
Replaces page 75.

TABLE

Proper Names	*Chemical Names and Synonyms*
Soluble Thiopentone	Sodium 5-ethyl-5-(1-methylbutyl) thiobarbiturate
Sulfamethazine	N^1-(4, 6-dimethyl-2-pyrimidyl) sulfanilamide: 2-(*p*-aminobenzene-sulphonamide)-4, 6-dimethylpyrimidine: Sulphadimidine
Sulfisoxazole	3, 4-dimethyl-5-sulfanilamido-isoxazole: Sulphafurazole
Tetracaine	2-dimethylaminoethyl-*p*-*n*-butylaminobenzoate: Amethocaine
Thiopentone	5-ethyl-5-(1-methylbutyl) thiobarbituric acid
Trimethadione	3, 5, 5-trimethyl-2, 4-oxazolidinedione: Troxidone

C.01.003. Except as provided in C.01.008 no person shall sell[1] a drug that is not labelled as required by these regulations.

C.01.004. Except as provided in these regulations the label[2] of a drug shall carry

(a) on the main panel of both the inner and the outer labels[2]

(i) the proper name and the standard under which the drug was manufactured which shall, if the standard is contained in any publication mentioned in SCHEDULE B[3] to the Act, be stated in full or by the abbreviation therein provided, or if the standard is provided by DIVISION 5 or DIVISION 6 of **Part** C of these regulations, the standard shall be designated as Canadian Standard Drug or C.S.D. or, if the drug is manufactured under Canadian licence[4] it shall be sufficient to state the Canadian licence number, and where there is a proprietary or brand name the proper name shall immediately precede or follow the said proprietary or brand name in type of not less than one-half the size thereof, or

(ii) if there is no proper name,[5] the common name,[6]

(b) on both the inner and the outer labels[2]

(i) the name of the manufacturer or distributor of the drug,

(ii) the address of the manufacturer or distributor, except that where the immediate container contains 5 millilitres or less, this statement need not be made on the inner label,

(iii) where a drug is intended for internal or parenteral use, the lot number[7] thereof,

(iv) adequate directions for use,

(v) the proper[5] or if there is no proper name the common name[6] of each medicinal ingredient contained therein except upon

(1) shipping cases or wrapping material,

(2) official drugs,[8]

(3) drugs sold on prescription,[9] or

(4) medicines registered under the Proprietary or Patent Medicine Act, and

(c) on the outer label[2]

(i) a correct statement of net contents in terms of weight, measure, or number, and

(ii) where the drug is intended for parenteral use,[10] the name and proportion of any preservative present therein.

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[1] See page 1.
[2] See page 1, A.01.010 (*e*) (*i*), C.01.006.
[3] See page 9.
[4] See C.03.001 (*b*), C.04.001 (*e*).
[5] See C.01.001 (*k*).
[6] See C.01.001 (*b*).
[7] The lot number should be preceded by the words "Lot Number" or by "Lot No." "Lot", or "(L)".
[8] See C.01.001 (*f*).
[9] See C.01.001 (*j*).
[10] See C.01.001 (*g*).

C.01.005. Any statement or information required by these regulations to be carried on a label[1] shall be legibly and conspicuously displayed thereon.

C.01.006. Where a package of a drug has only one label, that label shall contain all the information required by these regulations to be shown on both the inner and the outer labels.[1]

C.01.007. No reference, direct or indirect, to the Act or to these regulations shall be made upon any label of or in any advertisement for a drug unless such reference is a specific requirement of the Act or these regulations.

C.01.008. The provisions of C.01.004 do not apply to the label of a drug packaged from bulk on the premises where the drug is retailed; but where a package of a drug bears a statement, mark, or device regarding the ingredients declared therein in addition to

(a) the name of the drug,

(b) the name and address of the retailer,

(c) the net contents, and

(d) adequate directions for use,

it shall be labelled as required by the Act and by these regulations.

C.01.009. Where by any statute of the Parliament of Canada or any regulation made thereunder a standard or grade is prescribed for a drug and that standard is given a name or designation by such statute or regulation, no person shall on a label of or in any advertisement for that drug use that name or designation unless the drug conforms with the standard or grade.

C.01.010. Where it is necessary to provide adequate directions for the safe use of parenteral drugs and SCHEDULE F[2] drugs that are used in the treatment or prevention of any of the diseases, disorders, or abnormal physical states mentioned in SCHEDULE A[3] to the Act, such diseases, disorders or abnormal physical states may be mentioned in the inserts accompanying such drugs and to such extent, such drugs are hereby exempted from the provisions of Section 3 (1) of the Act.

C.01.011. Except as provided in C.01.012, no person shall sell[4] a drug in the form of a tablet which is intended to be swallowed whole, unless the tablet disintegrates in not more than 60 minutes when tested by the official method.[5]

C.01.012. The provisions of C.01.011 do not apply to tablets which are represented on the label as being enteric coated, or as having delayed action.

Limits of Drug Dosage

C.01.021. Except as provided in these regulations, no person shall sell[4] a drug for human use listed in the following table unless both the inner and the outer labels[1] carry a statement of

(a) the quantitative content of the drug, and

(b) the recommended single and daily dose except for preparations solely for external use, and

(c) adequate directions for use when the drug is recommended for children which shall be either

(i) the statement "CHILDREN: As directed by the physician", or

(ii) a suitably reduced maximum single and daily dose which shall not exceed the following:

Age in years	*Proportion of adult dose*
10–14	one-half
5–9	one-fourth
2–4	one-sixth
under 2 years	as directed by physician.

[1] See page 1, A.01.010 (*e*) (*i*), C.01.006.
[2] See page 10.
[3] See page 9.
[4] See page 1.
[5] See A.01.010 (*h*).

77, December 28, 1956.
Replaces page 77, September 6, 1956.

TABLE OF LIMITS OF DRUG DOSAGE FOR ADULTS

Item	External Use — Maximum Limit	Internal Use[1] — Maximum Dosage Unless otherwise stated, doses are in milligrams	
	Per cent	Single	Daily
Acetanilide and derivatives	—	65	195
Acetylsalicylic Acid and its salts	—	975	2·925 gm.
Aconitine, its preparations and derivatives	0·2	0·1	0·1
Adonis vernalis	—	65	195
Amylocaine Hydrochloride	1·0	0·0	0·0
Antimony, compounds of	—	3·3	13
Arsenious Oxide	—	2·2	6·5
Atropine, Methylatropine, and their salts	1·0	0·13	0·44
Belladonna and its preparations, on the basis of belladonna alkaloids	0·375	0·13	0·44
Benzene (Benzol)	—	—	—
Benzocaine	8·0	195	585
Beta-Naphthol	—	195	585
Bromides, calculated as Sodium Bromide (not more often than every 3 hours)	—	650	1·3 gm.
Butacaine Sulphate	1·0	0·0	0·0
Cantharides, Cantharidin, and their preparations, on the basis of cantharidin	0·03	0·0	0·0
Cantharides, blisters only	0·2	0·0	0·0
Cedar Oil	25·0	0·0	0·0
Chloral Hydrate	1·0	—	—
Chlorbutol (not more often than every 4 hours)	—	325	975
Cinchocaine Hydrochloride	1·0	0·0	0·0
Cinchocaine Hydrochloride, suppositories only	—	11	11
Colchicine and its salts	—	0·55	1·65
Colchicum and its preparations, on the basis of colchicine	—	0·27	0·81
Croton Oil	10·0	0·0	0·0
Cupric Arsenite	—	0·65	2·6
Ephedrine and its salts	—	11	32·5
Ephedrine and its salts, sprays	1·0	—	—
Epinephrine and its salts, sprays	1·0	—	—
Gelseminine (Gelsemine) and its salts (not to be repeated within 4 hours)	—	0·55	1·65
Gelsemium and its preparations, on the basis of the crude drug	—	16·2	48·6
Hellebore, Black (Christmas Rose)	—	0·0	0·0
Hellebore, Green, and its preparations, on the basis of the crude drug	—	0·0	0·0
Hydrocyanic (Prussic) Acid as 2 per cent solution	—	0·062 ml.	0·31 ml.
Hyoscine (Scopolamine) and its salts	0·5	0·325	0·975
Hyoscine aminoxide hydrobromide	0·5	0·325	0·975
Hyoscyamine and its salts	—	0·325	0·975
Hyoscyamus and its preparations, on the basis of hyoscyamus alkaloids	—	0·073	0·22
Iron Arsenate	—	2·2	6·5
Lobelia and its preparations, on the basis of the crude drug	—	130	390
Mercury and its compounds	—	—	—
Methylene Blue	—	130	390

[1] See C.01.001 *(d)*.

78, May 30, 1956.
Replaces page 78, March 9, 1955.

Item	External Use — Maximum Limit	Internal Use[1] — Maximum Dosage Unless otherwise stated, doses are in milligrams	
	Per cent	Single	Daily
Nux Vomica and its preparations, on the basis of strychnine	—	1·1	3·3
Penicillin, its salts and derivatives (in lozenges not exceeding 3,000 International Units per dose)	—	0·0	0·0
Phenacetin	—	650	1·95 gm.
Phenazone and compounds thereof	—	325	975
Phenol	2·0	32·5	260
Phosphorus	—	0·0	0·0
Potassium Chlorate	—	325	975
Potassium Chlorate, gargle	2·5	—	—
Procaine and its salts	—	—	—
Quinine Arsenate	—	4·35	13
St. Ignatius' Bean	—	32·5	97·5
Salicylic acid, and its salts	—	975	2·925 gm.
Salicylamide	—	975	2·925 gm.
Santonin	—	65	130
Sodium Arsenate Anhydrous	—	1·3	3·9
Sodium Cacodylate	—	16·2	48·6
Sodium Chlorate	—	325	975
Sodium Methylarsenate	—	32·5	97·5
Squill and its preparations, on the basis of the crude drug	—	32·5	97·5
Stramonium and its preparations, on the basis of stramonium alkaloids	—	0·16	0·65
Strychnine and its salts	—	1·1	3·3

Where drugs having similar physiological actions occur in combination, the dosage of each shall be proportionately reduced.

Accurate dosages may be expressed in either metric units or imperial units. If the dosage is expressed in both systems, then an approximation may be used for one expression, but such approximation must precede or follow the accurate statement by which the product will be judged and must be in brackets.

C.01.022. Notwithstanding C.01.021 (*b*), the recommended single and daily dosage of a drug

(a) intended to be burned and the smoke inhaled may be increased to ten times the oral dose, and

(b) intended for use as suppositories may be increased to 33 1/3 per cent in excess of the oral dose.

C.01.023. REVOKED P.C. 1956-1921 of 28th December, 1956.

C.01.024. The provisions of C.01.021, C.01.022 and C.01.023 do not apply to

(a) a drug sold to a drug manufacturer,

(b) a drug sold on prescription,[2] or

(c) the inner label[3] of a single-dose container.

[1] See C.01.001 (*d*).
[2] See C.01.001 (j).
[3] See page 1, A.01.010 (*e*) (*i*), C.01.006.

79, December 28, 1956.
Replaces page 79, May 30, 1956.

C.01.025. Both the inner and the outer labels[1] of a drug that carry a recommended single or daily dosage or a statement of concentration in excess of the limits provided by C.01.021 shall carry a caution that the product is to be used only on the advice of a physician.

C.01.026. The provisions of C.01.025 do not apply to
(a) a drug sold on prescription,[2] or
(b) the inner label[1] of a single-dose container.

C.01.027. No person shall advertise to the general public for human use, a drug that carries a recommended single or daily dosage or a statement of concentration in excess of the limits provided by C.01.021.

Schedule F Drugs

C.01.041. No person shall sell[3] a drug listed or described in SCHEDULE F[4] to the Act in these regulations referred to as SCHEDULE F Drug unless he has received a prescription[2] therefor, and such prescription shall
(a) if in writing, be retained by the dispenser thereof for a period of at least two years from the date of filling,
(b) if orally given, forthwith be reduced to writing and recorded in a record to be retained by the dispenser thereof for a period of at least two years, which record shall show
(i) the date and number of the prescription,[2]
(ii) the name and address of the person named therein,
(iii) the name and quantity of the drug specified therein,
(iv) the names of the persons issuing and receiving the prescription[2], and
(v) the directions for use given therewith, including whether or not the practitioner[5] directs the refilling of the prescription.[2]

C.01.042. No person shall refill a prescription[2] for a SCHEDULE F[4] Drug unless the practitioner[5] so directs and specifies the number of times that the same may be refilled.

C.01.043. The provision of C.01.041 do not apply to the sale of a SCHEDULE F[4] Drug to
(a) a drug manufacturer[6], or
(b) if the upper left quarter of the main panel of both the inner and outer label carries the symbol [P], to
(i) a practitioner[5],
(ii) a wholesale druggist,
(iii) a registered pharmacist,
(iv) a hospital certified by the Department of National Health and Welfare, or
(v) any Department of the Government of Canada or of a province upon an order signed by the Minister thereof or his duly authorized representative.

C.01.044. No person shall advertise to the general public for human use a SCHEDULE F[4] Drug.

C.01.045. No person other than
(a) a practitioner,[5]
(b) a drug manufacturer,[6]
(c) a wholesale druggist,
(d) a registered pharmacist, or
(e) a resident of a foreign country while a visitor in Canada
shall import a SCHEDULE F[4] Drug.

C.01.046. The provisions of C.01.041, C.01.043, and C.01.045 do not apply to a drug listed or described in PART II of SCHEDULE F[4] to the Act, if
(a) the drug is in a form not suitable for human use, or
(b) the main panel of both the inner and the outer labels[1] carries the words "For Agricultural Use Only" or "Agricultural Use Only" immediately following or preceding the proprietary or brand name, proper name,[7] or common name[8] in type not less than one-half as large as the largest type on the label.

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[1] See page 1, A.01.010 (*e*) (*i*), C.01.006.
[2] See C.01.001 (*j*).
[3] See page 1.
[4] See page 10.
[5] See C.01.001 (*i*).
[6] See A.01.010 (*g*).
[7] See C.01.001 (*k*).
[8] See C.01.001 (*b*).

C.01.047. The symbol ℞ shall not appear on the label of a drug unless it is required by these regulations.

Limits of Variability

C.01.061. Subject to C.01.062 where the contents of a package of a drug are expressed in terms of weight, measure, or number, no variations from the quantity declared on the label[1] are permitted other than the following

(a) variations due exclusively to weighing, measuring, or counting that occur in packaging conducted in accordance with good commercial practice, which variations are, except where the contents are expressed in terms of number, not to be such that the average content is less than the quantity declared on the label,[1] as determined by the official method,[2]

(b) variations due exclusively to differences in the capacity of containers resulting solely from unavoidable difficulties in manufacturing, but no greater variation is permitted because of the design of the containers than is permitted in the case of containers of similar capacity that can be manufactured so as to be of approximately uniform capacity,

(c) variations in weight or measure that unavoidably result from the ordinary and customary exposure of the package to evaporation or to the absorption of water under normal atmospheric conditions,

(d) for a drug, other than an official drug,[3] put up in ampoules or vials and not prepared ready for injection, variations within the limits stated in the following table as determined by an acceptable method[4]

Labelled amount per ampoule or vial	Limits of variation from the labelled amount
More than 50 milligrams	Not less than 95 per cent and not more than 105 per cent
More than 25 milligrams and not more than 50 milligrams	Not less than 90 per cent and not more than 110 per cent
Not more than 25 milligrams	Not less than 80 per cent and not more than 120 per cent

except that if the drug consists of several ingredients, the amount of each ingredient so dispensed shall be not less than 90 per cent and not more than 110 per cent of the amount calculated from the label description, and

(e) for a drug, other than an official drug,[3] put up in tablet or any other individual dosage or dispensing form other than in ampoules or vials, variations within the limits stated in the following table as determined by an acceptable method[4]

Labelled amount per tablet	Limits of variation from the labelled amount
Not less than 5 grains	Not less than 94 per cent and not more than 106 per cent
Not less than 1/2 grain and less than 5 grains	Not less than 93 per cent and not more than 107 per cent
Not less than 1/20 grain and less than 1/2 grain	Not less than 92 per cent and not more than 108 per cent
Not less than 1/100 grain and less than 1/20 grain	Not less than 91 per cent and not more than 109 per cent
Less than 1/100 grain	Not less than 90 per cent and not more than 110 per cent

[1] See page 1, A.01.001 (*e*) (*i*), C.01.006.
[2] See A.01.010 (*h*).
[3] See C.01.001 (*f*).
[4] See A.01.010 (*a*).

except that

(i) glyceryl trinitrate shall contain not less than 85 per cent and not more than 115 per cent of the labelled amount, and

(ii) if the drug consists of several ingredients, the amount of each ingredient so dispensed shall be not less than 90 per cent and not more than 110 per cent of the amount calculated from the label description.

C.01.062. Notwithstanding C.01.061 where the contents of a package of a drug are expressed in terms of minimum weight, measure, or number, the contents of the package shall not be less than the minimum expressed.

C.01.063. Where a drug is put up in ampoules ready for parenteral use,[1] each ampoule of the drug shall contain an excess volume sufficient to permit the withdrawal of the volume declared on the label.[2]

C.01.064. Where a drug is prepared for parenteral[1] use and contains a preservative ingredient, such ingredient

(a) shall be added only in an amount that is non-toxic and harmless in the dosage in which the drug is recommended to be used, and

(b) shall not interfere with the therapeutic properties of the drug.

C.01.065. No person shall sell[3] a drug that is prepared for parenteral[1] use unless the drug in its final container is tested, by an acceptable method,[4] where such a test can be carried out, for identity, the presence of pyrogens, sterility and safety, and when so tested is found to be true to name, free of pyrogens, sterile and safe when used according to directions.

C.01.066. The immediate container of a drug prepared for parenteral use[1] shall be of such material and construction that

(a) no deleterious substance is yielded to the contents thereof, and

(b) if made of glass, it permits inspection of the contents.

C.01.067. No person shall sell a drug that is a hypodermic tablet that does not completely dissolve in and form a clear solution with water.

Mercuric Chloride Tablets

C.01.071. No person shall sell[3] mercuric chloride tablets for household use that are packaged in lots of two hundred or less, unless

(a) such tablets are

(i) of an irregular or angular shape,

(ii) coloured blue, and

(iii) packed in an immediate container that is readily distinguishable by touch, and

(b) the main panel of both the inner and the outer labels[2] carries in prominent type and in a colour contrasting to that of such labels

(i) the design of a skull and cross-bones, and

(ii) the word "Poison".

Strychnine, Methyl Salicylate, Ferrous Sulphate

C.01.072. No person shall sell[3]

(a) a drug containing strychnine or its salts,

(b) a drug containing more than 5 per cent methyl salicylate, or

(c) capsules or tablets containing more than 60 mgs. of elemental iron in the form of ferrous sulphate per capsule or tablet,

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[1] See C.01.001 (*g*).
[2] See page 1, A.01.010 (*e*) (*f*), C.01.006.
[3] See page 1.
[4] See A.01.010 (*a*).

unless the main panel of both the inner and the outer labels[1] carries the words "CAUTION: Keep out of reach of children" or "CAUTION: Keep this and all medication out of the reach of children".

Salicylic Acid, Acetylsalicylic Acid, Salicylamide

C.01.073. No person shall sell[2] a drug containing salicylic acid or its salts, acetylsalicylic acid or its salts or salicylamide which is recommended for children unless both the inner and the outer labels[1] carry a cautionary statement to the effect that the drug is not to be administered to children under 2 years of age except on the advice of a physician.

Epinephrine Solutions

C.01.081. Solutions of epinephrine, its salts, or optical isomers for inhalation use shall carry on both the inner and the outer labels[1]

(a) a statement of the concentration, and strength in terms of epinephrine, and

(b) the lot number.[3]

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[1] See page 1, A.01.010 (*e*) (*i*), C.01.006.
[2] See page 1.
[3] The lot number should be preceded by the words "Lot Number" or by "Lot No.", "Lot" or "(L)".

Disinfectants

C.01.091. A preparation that is represented to be of a value as a disinfectant, germicide or the like, shall carry on both the inner and the outer labels[1]

(a) a statement of the chemical name and proportion or amount of each active ingredient,

(b) for preparations of phenolic type or of natural oils, except for soaps and ointments, a statement of the phenol co-efficient of the preparation as determined by an acceptable method,[2]

(c) for preparations containing available chlorine a statement of the percentage of such chlorine content, and

(d) the lot number.[3]

Synthetic Sweeteners

C.01.101. Saccharin, sodium salts of saccharin, or sodium or calcium salts of cyclohexyl sulphamic acid shall carry on both the inner and the outer labels[1] the statement "(naming the synthetic sweetener) is a chemical substance without nutritive value and should be used in moderation".

Containers for Collapsible Tubes

C.01.121. No person shall sell[4] a drug in a collapsible tube packed in a carton if the dimensions of the carton exceed

(a) for all tubes without chip-board protectors, and tubes of less than 1 1/4" diameter with chip-board protectors

(i) length—over-all tube length filled and clipped plus 8/32",

(ii) height—diameter of tube plus 4/32", and

(iii) width—1·25 times tube diameter plus 4/32", and

(b) for all tubes of 1 1/4" diameter and over, with chip-board protectors

(i) length—over-all tube length filled and clipped plus 10/32",

(ii) height—diameter of tube plus 4/32", and

(iii) width—1·25 times tube diameter plus 4/32".

C.01.122. Notwithstanding C.01.121, when an applicator is essential to the use of a drug sold in a collapsible tube packed in a carton, and such applicator is included in the carton, the dimensions of the carton may exceed those set out in C.01.121 provided that the main panel of the label of the carton clearly indicats that it is combination package.

New Drugs[5]

C.01.301. No person shall sell[4] a new drug[5] unless there has been filed with the Minister in a form, manner and content satisfactory to him for a period of not less than two months prior to the sale or for such other time not exceeding a further four months, as the Minister prescribes, a submission that includes

(a) a description of the drug, including its proper name[6] if any, or if it has no proper name the name under which it is proposed to be sold,

(b) a statement of the amounts of all ingredients, route of administration, proposed dosage, the claims to be made for such drug, and a description of the pharmaceutical forms in which it is proposed to be sold,

(c) details of its method of manufacture where necessary to evaluate its safety,

(d) detailed reports of tests made to establish the safety of the drug for the purpose and under the conditions of use recommended,

(e) particulars of tests applied to control potency, purity, and safety of the drug,

(f) a draft in duplicate of each label[1] proposed to be used, and

(g) a sample of the drug in the pharmaceutical form in which it is proposed to be sold.

C.01.302. Notwithstanding C.01.301, a manufacturer may sell[4] a new drug,[5] to investigators qualified to use such drug, for the sole purpose of obtaining clinical and scientific data with respect to safety, stability, dosage, or efficacy, if

(a) the Minister is first informed of the identifying name or mark by which the drug can be recognized,

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[1] See page 1, A.01.010 (*e*) (*i*), C.01.006.
[2] See A.01.010 (*a*).
[3] The lot number should be preceded by the words "Lot Number" or by "Lot No.", "Lot" or "(L.)".
[4] See page 1.
[5] See C.01.001 (*e*)
[6] See C.01.001 (*k*).

(b) both the inner and the outer labels[1] carry the statement "For Experimental Use By Qualified Investigators Only",

(c) the manufacturer,[2] prior to making a shipment takes the necessary steps to ensure that any person to whom the drug is sold is a qualified investigator and that he has adequate facilities for the investigation to be conducted by him, and that such drug will be used solely by him or under his direction for the investigation, and

(d) the manufacturer[2] keeps accurate records of such distribution and makes these records available for inspection upon the request of an inspector.

Antibiotics[3]

C.01.401. An antibiotic for other than parenteral[4] use shall, in addition to meeting the requirements of C.01.004, carry on both the inner and the outer labels[1]

(a) the potency of the drug expressed in terms of International Units where established, or, if no International Unit has been established, in terms of units, milligrams or fractions of a gram, per gram in the case of solids or viscous liquids, per millilitre in the case of other liquids, or per individual dosage or dispensing form for antibiotic preparations put up in individual dosage or dispensing form,

(b) a lot number[5] assigned by the manufacturer,[3] and

(c) the expiration date.[6]

C.01.402. The manufacturer[3] of an antibiotic or any preparation thereof shall determine a date therefor, in this DIVISION called the expiration date, after which the drug is not recommended for use and in determining such a date the manufacturer shall have regard to the stability of the drug and shall, on request, submit to the Director information respecting evidence supporting the determination of such date.

Bacitracin

C.01.410. **Bacitracin** shall be an antibiotic substance produced during the growth of *Bacillus subtilis.*

C.01.411. When bacitracin is dissolved in distilled water and diluted to a concentration of 10,000 units per millilitre the solution shall be clear, and shall have a pH of not less than 5·5 and not more than 7·5.

C.01.412. Bacitracin shall not contain

(a) more than 5 per cent moisture, and

(b) less than 40 units per milligram except that, if intended for systemic medication, it shall contain not less than 50 units per milligram

as determined by an acceptable method.[7]

Carbomycin

C.01.420. **Carbomycin** shall be an antibiotic substance produced during the growth of *Streptomyces halstedii.*

C.01.421. When 100 milligrams of carbomycin are dissolved in 10 millilitres of distilled water the solution shall be clear, and shall have a pH of not less than 5·5 and not more than 7·5.

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[1] See page 1, A.01.010 (*e*) (*i*), C.01.006.
[2] See A.01.010 (*g*).
[3] See C.01.001 (*a*).
[4] See C.01.001 (*g*).
[5] The lot number should be preceded by the words "Lot Number" or by "Lot No.", "Lot" or by "(L.)".
[6] See C.01.001 (*c*).
[7] See A.01.010 (*a*).

C.01.422. Carbomycin shall not contain

(a) more than 3 per cent volatile matter, and

(b) less than 750 micrograms of carbomycin per milligram

as determined by an acceptable method.[1]

Chloramphenicol

C.01.430. **Chloramphenicol** shall be an antibiotic substance with the chemical formula D(-)-threo-1-*p*-nitrophenyl-2-dichloroacetamido-1, 3-propanediol produced synthetically or during the growth of *Streptomyces venezuelae.*

C.01.431. A saturated aqueous solution of chloramphenicol shall have a pH of not less than 4·5 and not more than 7·5.

C.01.432. Chloramphenicol shall not contain

(a) less than 900 micrograms of chloramphenicol per milligram, and

(b) histamine or histamine-like substance

as determined by an acceptable method.[1]

Chlortetracycline

C.01.440. **Chlortetracycline** shall be an antibiotic substance produced during the growth of *Streptomyces aureofaciens.*

C.01.441. When chlortetracycline is dissolved in distilled water and diluted to contain 10 milligrams of chlortetracycline per millilitre, the solution shall be clear, and shall have a pH of not less than 2·3 and not more than 3·3.

C.01.442. Chlortetracycline shall not contain

(a) more than 2·0 per cent moisture,

(b) less than 900 micrograms of chlortetracycline per milligram, and

(c) histamine or histamine-like substance

as determined by an acceptable method.[1]

Erythromycin

C.01.450. **Erythromycin** shall be an antibiotic substance produced during the growth of *Streptomyces erythreus.*

C.01.451. A saturated aqueous solution of erythromycin shall have a pH of not less than 8·0 and not more than 10·5.

C.01.452. Erythromycin shall not contain

(a) more than 10 per cent moisture as determined by the official method,[2] and

(b) less than 850 micrograms of erythromycin per milligram as determined by an acceptable method.[1]

Neomycin

C.01.460. **Neomycin** shall be an antibiotic substance produced during the growth of *Streptomyces fradiae.*

C.01.461. When 330 milligrams of neomycin sulphate is dissolved in 10 millilitres of distilled water the solution shall be clear, and shall have a pH of not less than 5·0 and not more than 7·5.

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[1] See A.01.010 (*a*).
[2] See A.01.010 (*h*).

C.01.462. Neomycin sulphate shall not contain

(a) more than 8 per cent moisture, and

(b) less than 650 micrograms of neomycin per milligram

as determined by an acceptable method.[1]

Oxytetracycline

C.01.470. **Oxytetracycline** shall be an antibiotic substance produced during the growth of *Streptomyces rimosus.*

C.01.471. An aqueous solution of 10 milligrams of oxytetracycline hydrochloride per millilitre shall have a pH of not less than 2·3 and not more than 2·9.

C.01.472. Oxytetracycline hydrochloride shall not contain

(a) more than 1·5 per cent volatile matter,

(b) less than 800 micrograms of oxytetracycline per milligram, and

(c) histamine or histamine-like substance when intended for parenteral use

as determined by an acceptable method.[1]

Penicillin

C.01.480. **Penicillin** shall be one or more of the antibiotic substances produced during the growth of fungi such as *Penicillium notatum* or *Penicillium chrysogenum.*

Crystalline Penicillin

C.01.490. **Crystalline Penicillin** shall be the heat-stable crystalline salt of one or more kinds of penicillin, e.g. F, G, K, X.

C.01.491. No person shall sell crystalline penicillin described as a single kind of crystalline penicillin salt unless it contains more than 85 per cent of the named kind of crystalline penicillin salt.

C.01.492. A mixture of crystalline penicillin salts shall carry on both the inner and the outer labels[2] a statement of the quantitative composition by weight of the mixture in terms of the kinds of crystalline penicillin salts present.

C.01.493. The provision of C.01.492 does not apply to components of the mixture present in amounts of less than 15 per cent of the whole.

C.01.494. When crystalline penicillin is dissolved in distilled water and diluted to contain 10,000 International Units per millilitre the solution shall be clear, and shall have a pH of not less than 5·0 and not more than 7·5.

C.01.495. Crystalline penicillin shall not contain more than 1·5 per cent moisture as determined by an acceptable method.[1]

C.01.496. Crystalline sodium penicillin G shall contain not less than 1,500 International Units of penicillin per milligram as determined by an acceptable method.[1]

C.01.497. Crystalline potassium penicillin G shall contain not less than 1,400 International Units of penicillin per milligram as determined by an acceptable method.[1]

Procaine Penicillin

C.01.510. **Procaine Penicillin** shall be the procaine salt of the acid of penicillin.

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[1] See A.01.010 (*a*).
[2] See page 1, A.01.010 (*e*) (*i*), C.01.006.

C.01.511. A saturated aqueous solution of procaine penicillin shall have a pH of not less than 5·0 and not more than 7·5.

C.01.512. Procaine penicillin shall not contain more than 4·5 per cent moisture, and procaine penicillin in oil shall not contain more than 1·5 per cent moisture as determined by an acceptable method.[1]

C.01.513. Procaine penicillin shall contain not less than 900 International Units of penicillin per milligram as determined by an acceptable method.[1]

Benzathine Penicillin G

C.01.520. **Benzathine Penicillin G** shall be the crystalline N, N′-dibenzylethylenediamine salt of penicillin G.

C.01.521. Benzathine penicillin G shall not contain

(a) more than 8 per cent moisture, and

(b) less than 1,050 International Units of penicillin per milligram,

as determined by an acceptable method.[1]

C.01.522. A saturated aqueous solution of benzathine penicillin G shall have a pH of not less than 5·0 and not more than 7·5.

Penethamate Hydriodide

C.01.530. **Penethamate Hydriodide** shall be the crystalline diethylaminoethyl ester hydriodide salt of penicillin G.

C.01.531. A saturated aqueous solution of penethamate hydriodide shall have a pH of not less than 4·0 and not more than 6·5.

C.01.532. Penethamate hydriodide shall not contain

(a) more than 1·0 per cent moisture, and

(b) less than 900 International Units of penicillin per milligram, as determined by an acceptable method.[1]

Penicillin G l-Ephenamine

C.01.540. **Penicillin G *l*-Ephenamine** shall be the heat-stable crystalline *laevo*-N-methyl-1, 2-diphenyl-2-hydroxyethylamine salt of penicillin G, prepared from crystalline penicillin G and crystalline *dl*-N-methyl-1, 2-diphenyl-2-hydroxyethylamine hydrochloride.

C.01.541. A saturated aqueous solution of penicillin G *l*-ephenamine shall have a pH of not less than 5·0 and not more than 7·5.

C.01.542. Penicillin G *l*-ephenamine shall not contain

(a) more than 1·5 per cent moisture, and

(b) less than 900 International Units of penicillin per milligram

as determined by an acceptable method.[1]

Polymyxin B

C.01.550. **Polymyxin B** shall be an antibiotic substance produced during the growth of various strains of *Bacillus polymyxa*.

C.01.551. When 10 milligrams of polymyxin B sulphate are dissolved in 10 millilitres of distilled water the solution shall have a pH of not less than 5·0 and not more than 7·5.

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[1] See A.01.010 (*a*).

C.01.552. Polymyxin B shall not contain
(a) more than 7·5 per cent moisture,
(b) less than 3,800 units of polymyxin B per milligram unless prepared for non-parenteral use, in which case it shall contain not less than 5,000 units of polymyxin B per milligram, and
(c) histamine or histamine-like substance
as determined by an acceptable method.[1]

Streptomycin

C.01.560. **Streptomycin** shall be an antibiotic substance produced during the growth of *Streptomyces griseus.*

C.01.561. When streptomycin is dissolved in distilled water and diluted to contain 200,000 micrograms of streptomycin base per millilitre, the solution shall be clear and shall have a pH of not less than 4·5 and not more than 7·0 except that streptomycin solution sold as such shall have a pH of not less than 4·5 and not more than 8·0.

C.01.562. Streptomycin shall not contain
(a) more than 5·0 per cent moisture
(b) less than 650 micrograms of streptomycin base per milligram,
(c) histamine or histamine-like substance, and
(d) more than 250 parts per million of contaminating heavy metals, and if contaminating heavy metals are present not more than 50 parts per million may be lead
as determined by an acceptable method.[1]

C.01.563. **Dihydrostreptomycin** shall be a hydrogenated derivative of streptomycin and shall conform to the requirements for streptomycin in C.01.560 to C.01.562 except that the potency shall be expressed in terms of dihydrostreptomycin.

Streptomycylidene Isonicotinyl Hydrazine

C.01.570. **Streptomycylidene Isonicotinyl Hydrazine** shall be the crystalline sulphate compound of streptomycin sulphate and isoniazid.

C.01.571. When 0·2 gram of streptomycylidene isonicotinyl hydrazine is dissolved in 1 millilitre of distilled water the solution shall have a pH of not less than 4·5 and not more than 7·5.

C.01.572. Streptomycylidene isonicotinyl hydrazine shall not contain
(a) more than 5 per cent moisture,
(b) less than 583 micrograms of streptomycin base per milligram,
(c) less than 13·75 per cent isoniazid, and
(d) histamine or histamine-like substance
as determined by an acceptable method.[1]

Tyrothrycin

C.01.580. **Tyrothrycin** shall be an antibiotic substance produced during the growth of *Bacillus brevis*, and shall consist of a mixture of tyrocidine and gramicidin.

Viomycin

C.01.590. **Viomycin** shall be an antibiotic substance produced during the growth of *Streptomyces puniceus.*

C.01.591. When one gram of viomycin sulphate is dissolved in 10 millilitres of distilled water the solution shall have a pH of not less than 4·5 and not more than 7·0.

C.01.592. Viomycin sulphate shall not contain
(a) more than 7 per cent moisture,
(b) less than 700 micrograms of viomycin per milligram, and
(c) histamine or histamine-like substance
as determined by an acceptable method.[1]

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[1] See A.01.010 (*a*).

Veterinary Drugs

C.01.600. No person shall sell for veterinary use a drug listed in the Table of Limits of Drug Dosage for Adults unless both the inner and the outer labels[1] carry, in addition to the requirements of C.01.004

(a) the quantitative content of the drug,

(b) except for drugs in a form not suitable for human use, the statement "For Veterinary Use Only" or "Veterinary Use Only".

C.01.601. The provisions of C.01.041, C.01.043 and C.01.045 do not apply to a drug listed or described in PART II of SCHEDULE F[2] to the Act, if

(a) the drug is in a form not suitable for human use, or

(b) the main panel of both the inner and the outer labels[1] carries the words "For Veterinary Use Only" or "Veterinary Use Only" immediately following or preceding the proprietary or brand name, proper name, or common name in type not less than one-half as large as the largest type on the label.

C.01.602. The provisions of C.01.401 and C.01.402 do not apply to an antibiotic in amounts less than 50 parts per million contained in an animal food.

C.01.603. The provisions of C.01.401 (*b*) and (*c*) and C.01.402 do not apply to an antibiotic in amounts greater than 50 parts per million contained in an animal food.

C.01.604. Both the inner and the outer labels[1] of a veterinary drug represented as containing a vitamin shall, in addition to meeting the requirements of C.01.004, carry

(a) a statement of the amount of each vitamin present in the drug, expressed in terms of the proper name only of the vitamin in

(i) International Units per gram or per millilitre for vitamin A, provitamin A, vitamin D, and vitamin E,

(ii) milligrams per gram in the case of solids or viscous liquids, or per millilitre in the case of other liquids, for thiamine, riboflavin, niacin, niacinamide, pyridoxine, *d*-pantothenic acid, *d*-panthenol, folic acid, ascorbic acid, and vitamin K,

(iii) micrograms per gram in the case of solids or viscous liquids, or per millilitre in the case of other liquids, for biotin, and vitamin B_{12},

(iv) Oral Units for vitamin B_{12} with intrinsic factor concentrate, or

(v) for vitamin products put up in individual dosage or dispensing form, the specified units per individual dosage or dispensing form,

(b) except for drugs in a form not suitable for human use, the statement "For Veterinary Use Only" or "Veterinary Use Only".

C.01.605. An antibiotic for parenteral use that is recommended for veterinary use only shall, in addition to meeting the requirements of C.01.004, carry on both the inner and the outer labels[1]

(a) the potency of the drug expressed in terms of International Units where established, or, if no International Unit has been established, in terms of units, milligrams or fractions of a gram, per gram in the case of solids or viscous liquids, per millilitre in the case of other liquids, or per individual dosage or dispensing form for antibiotic preparations put up in individual dosage or dispensing form,

(b) the expiration date, and

(c) the statement "For Veterinary Use Only" or "Veterinary Use Only".

C.01.606. The label of an antibiotic sold for the treatment of mastitis shall carry a warning to the effect that milk from treated quarters should not be used for human consumption or marketed for making cheese for at least 72 hours after the last treatment.

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[1] See page 1, A.01.010 (*e*) (*i*).
[2] See page 10.

88A, May 30, 1956.
Replaces page 88A, August 10, 1955.

C.01.607. Notwithstanding the provisions of C.01.004 *(b)* (iii), C.02.004 *(a)* (iv), and C.02.005 *(a)* (iii), the declaration of a lot number[1] is not required on the label[2] of an animal feeding-stuff containing a drug.

[1] See A.01.010 (*f*)
[2] See page 1.

Sex Hormones

C.02.001. In these regulations

(a) "Canadian Reference Standard" means when used with reference to a sex hormone product the standard established by the Director from whom portions thereof for comparative testing may be obtained, and

(b) "sex hormone" means any synthetic or natural product represented as having oestrogenic, androgenic, gonadotrophic or progestational properties and any drug consisting in whole, or in part, of sex gland tissue or any extract thereof.

C.02.002. When there is an international standard or a Canadian Reference Standard for the potency of a sex hormone, the potency of the sex hormone shall be expressed in terms of such standard as determined by an acceptable method,[1] but where no such standard exists the manufacturer[2] of a sex hormone product shall

(a) submit a suitable quantity of the product to be used as a Canadian Reference Standard for checking the uniformity of the product, or

(b) where stable standards cannot be furnished by the manufacturer,[2] include with every package of the sex hormone details of the unit of potency and the method of assay used.

C.02.003. The proper names of

(a) natural crystalline sex hormones shall be

(i) **Androsterone,**
(ii) **Oestriol,**
(iii) **Oestradiol,**
(iv) **Oestrone,**
(v) **Progesterone,**
(vi) **Testosterone,**

and esters and derivatives of these,

(b) pure synthetic sex hormones shall be the name assigned in any of the publications mentioned in SCHEDULE B[3] to the Act,

(c) mixed or conjugated sex hormones shall be

(i) **Androgenic Substance,**
(ii) **Conjugated Oestrogenic Substance,**
(iii) **Oestrogenic Substance,**
(iv) **Progestational Substance,** and

(d) gonadotrophins shall be **Gonadotrophin** with a qualifying word to indicate the source.

C.02.004. The provisions of C.01.004 do not apply to a sex hormone but a sex hormone shall carry

(a) on both the inner and the outer labels[4]

(i) the name of the manufacturer,[2] or distributor,
(ii) the proper name,[5] and where there is a proprietary or brand name the proper name shall immediately precede or follow the said proprietary or brand name in type of not less than one-half the size thereof,
(iii) the potency,
(iv) the lot number,[6] and

(b) on the outer label[4]

(i) the address of the manufacturer,[2] or distributor,
(ii) the name of the solvent or vehicle used in products in liquid form,
(iii) the name and amount of any preservative,
(iv) a statement of net contents in terms of weight, measure, or number,
(v) for chorionic gonadotrophins in aqueous solution, the expiration date[7] that shall be not later than 24 months after the date of passing a potency test, and
(vi) for pregnant mare serum gonadotrophin in aqueous solution, the expiration date[7] that shall be not later than 12 months after the date of passing a potency test.

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[1] See A.01.010 (*a*).
[2] See A.01.010 (*g*).
[3] See page 9.
[4] See page 1, A.01.010 (*e*) (*i*), C.01.006.
[5] See C.01.001 (*k*).
[6] The lot number should be preceded by the words "Lot Number" or by "Lot No.", "Lot" or "(L.)"
[7] See C.01.001 (*c*).

89, May 30, 1956.
Replaces page 89, August 10, 1955.

C.02.005. The provisions of C.01.004 and C.02.004, do not apply to a sex hormone consisting in whole, or in part of sex gland tissue or extracts thereof for which no proper name[1] is prescribed in C.02.003, and for which no standard of potency exists, but such sex hormone shall carry

(a) on both the inner and the outer labels[2]

(i) the name of the manufacturer,[3]

(ii) the common name,[4]

(iii) the lot number,[5] and

(b) on the outer label[2]

(i) the address of the manufacturer,[3]

(ii) the name of the solvent or vehicle used in products in liquid form,

(iii) the name and amount of any preservative,

(iv) a statement of net contents in terms of weight, measure, or number, and

(v) the statement, "The sex gland tissue (or extract as the case may be) in this preparation has no known therapeutic sex hormone action".

C.02.006. No person shall sell for administration to poultry that may be consumed as food any substance having oestrogenic activity.

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[1] See C.01.001 (*k*).
[2] See page 1, A.01.010 (*e*) (*i*), C.01.006.
[3] See A.01.010 (*g*).
[4] See C.01.001 (*b*).
[5] The lot number should be preceded by the words "Lot Number" or by "Lot No.", "Lot" or "(L.)".

Schedule C Drugs[1]

C.03.001. In this DIVISION

(a) "drug" means any drug mentioned or described in SCHEDULE C to the Act,

(b) "licence" or "Canadian licence" means the prescribed form and manner used by the Minister to indicate that the premises in which a drug was in whole or in part manufactured, and the process and conditions of manufacture therein are suitable to ensure that the drug is not unsafe for use,

(c) "manufacturer" means a person to whom a licence has been issued as provided in this DIVISION,

(d) "master lot" means a quantity of a drug from which a lot is prepared for sale by subsequent dilution or mixture.

C.03.002. This DIVISION does not apply to a drug labelled for veterinary use only.

C.03.003. An application for a licence and for the renewal thereof shall be made on the form prescribed therefor in Appendix III[2] and shall be accompanied by a fee of ten dollars payable to the Receiver General of Canada.

C.03.004. As a condition of the issuance and continuation of a licence, the Minister may require

(a) inspection to be made at any time during normal business hours of

(i) the premises in which a drug, which is the subject of an application, is manufactured, and
the process and conditions of manufacture therein,

(ii) the qualifications of technical staff concerned with the manufacture of the drug, and

(iii) the records relevant to the drug,

(b) that a manufacturer[3] shall supply, on request, samples of any material used in the production of a drug and samples of the finished drug

to ensure that the drug will not be unsafe for use.

C.03.005. As a condition of the issuance and continuation of a licence the Minister may require a manufacturer[3] who manufactures a drug outside Canada under a Canadian licence

(a) to designate a representative in Canada,

(b) to furnish the name and address of such representative who shall maintain satisfactory records of the distribution of the drug in Canada.

C.03.006. A licence shall be in the form prescribed therefor in Appendix III[2] and shall expire on the 31st of March of each year.

C.03.007. The Minister may make a charge to cover the necessary living and travelling expenses of any inspector in connection with any inspection as required by these regulations.

C.03.008. The Minister may refuse to issue a licence, or may cancel, or may suspend any licence so issued in whole, or as regards to any drug in respect of which it is issued, and may impose such conditions for the removal of such suspension or the reinstatement of the licence as he considers necessary to ensure that any drug for which the licence is issued will not be unsafe for use.

C.03.009. Every manufacturer[3] shall keep records in a satisfactory form respecting the manufacture, testing, and distribution of each lot of a drug manufactured by him, giving the date of such manufacture, testing or distribution, and make these records available to the Minister on request.

C.03.010. The Minister may refuse to issue, or may cancel or suspend the licence[4] of a manufacturer[3] who does not maintain his premises under the direct control and personal supervision of a responsible, qualified person.

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[1] See page 9.
[2] See page 142.
[3] See C.03.001 (*c*).
[4] See C.03.001 (*b*).

C.03.011. A manufacturer[1] shall notify the Minister promptly of changes in

(a) responsible qualified personnel,

(b) premises in which the drug is manufactured, and process and conditions of manufacture therein.

C.03.012. Upon written request from the Director a manufacturer[1] shall submit protocols of tests together with samples of any lot or master lot of any drug prior to its being sold, and no person shall sell[2] any lot of which the protocol or sample fails to meet the requirements of these regulations.

C.03.013. No person shall manufacture a drug from animal tissue unless such tissue has been obtained from a healthy animal free from infectious disease.

C.03.014. The provisions of C.01.004 do not apply to a drug as defined in this DIVISION but every package of such drug shall carry

(a) on both the inner and the outer labels[3]

(i) the proper name of the drug as specified in the licence, and where there is a proprietary or brand name the proper name shall immediately precede or follow the said proprietary or brand name in type of not less than one-half the size thereof,

(ii) the name of the manufacturer,[1]

(iii) the potency of the drug,

(iv) the lot number,[4]

(v) a complete list of the medicinal ingredients,

(vi) adequate directions for use, and

(b) on the outer label[3]

(i) the address of the manufacturer,[1]

(ii) the Canadian licence[5] number of the manufacturer,[1]

(iii) the expiration date[6] of the drug,

(iv) the name and amount of any preservative in the drug, and

(v) a statement of the net contents in terms of weight, measure, or number.

Liver Extract Injectable

C.03.030. **Liver Extract Injectable** shall be the soluble, thermostable fraction of mammalian liver that, when administered to persons affected with pernicious anaemia, produces a remission of the disorder.

C.03.031. The Canadian Reference Standard for liver extract injectable shall be vitamin B_{12} (cyanocobalamin) and shall be kept in the Food and Drug Laboratories from whence portions for comparative testing may be had upon application to the Director.

C.03.032. No person shall sell liver extract injectable to which has been added vitamin B_{12} in any form.

C.03.033. No person shall sell[2] liver extract injectable unless

(a) each filling of each lot has been tested for potency by the official method,[7] and

(b) both the inner and the outer labels[3] carry a statement of the potency expressed in terms of vitamin B_{12} (cyanocobalamin) which shall follow the name *liver extract injectable* without any intervening text or design.

C.03.034. No person shall sell[2] liver extract injectable except in potencies equivalent to either 10 micrograms or 20 micrograms of vitamin B_{12} (cyanocobalamin) per cubic centimetre.

C.03.035. Multiple dose containers of liver extract injectable shall contain a preservative.

C.03.036. A manufacturer[1] of liver extract injectable shall determine the expiration date[6] therefor and, in determining such a date, the manufacturer shall have regard to the stability of the drug and shall, on request, submit to the Director information respecting evidence supporting the determination of such date.

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[1] See C.03.001 (*c*).
[2] See page 1.
[3] See page 1, A.01.010 (*e*) (*i*), C.01.006.
[4] The lot number should be preceded by the words "Lot Number" or by "Lot No.", "Lot" or "(L.)"
[5] See C.03.001 (*b*).
[6] See C.01.001 (*c*).
[7] See A.01.001 (h).

C.03.037. **Liver Extract Injectable with other medication** shall meet all the requirements of liver extract injectable and the true nature and amount of the added medication shall be stated on the label[1] with observance of any requirement of these regulations in respect of such added medication, and the words *other medication* may be replaced by the proper name of such added medication.

C.03.038. **Liver Extract Injectable Crude** shall be that fraction of liver extract injectable obtained by stopping the process of extraction at such a stage that the final product is derived from an alcohol solution of a concentration not greater than 70 per cent by volume of ethyl alcohol.

C.03.039. The Canadian Reference Standard for liver extract injectable crude shall be vitamin B_{12} (cyanocobalamin) and shall be kept in the Food and Drug Laboratories from whence portions for comparative testing may be had upon application to the Director.

C.03.040. No person shall sell[2] liver extract injectable crude to which has been added vitamin B_{12} in any form.

C.03.041. No person shall sell[2] liver extract injectable crude unless

(a) each filling of each lot has been tested for potency by the official method,[3] and

(b) both the inner and the outer labels[1] carry a statement of the potency expressed in terms of vitamin B_{12} (cyanocobalamin) which shall follow the name *liver extract injectable crude* without any intervening text or design.

C.03.042. No person shall sell[2] liver extract injectable crude except in potencies equivalent to either 1 microgram or 2 micrograms of vitamin B_{12} (cyanocobalamin) per cubic centimetre.

C.03.043. Multiple dose containers of liver extract injectable crude shall contain a preservative.

C.03.044. A manufacturer[4] of liver extract injectable crude shall determine the expiration date[5] therefor and, in determining such a date, the manufacturer shall have regard to the stability of the drug and shall, on request, submit to the Director information respecting evidence supporting the determination of such date.

C.03.045. **Liver Extract Injectable Crude with other medication** shall meet all the requirements of liver extract injectable crude and the true nature and amount of the added medication shall be stated on the label[1] with observance of any requirement of these regulations in respect of such added medication, and the words *other medication* may be replaced by the proper name of such added medication.

Insulin

C.03.050. Insulin shall be the active principle of the pancreas that affects the metabolism of carbohydrates in the animal body and is of value in the treatment of *diabetes mellitus*.

C.03.051. The zinc-insulin crystals used in insulin preparations shall contain

(a) not less than 21 International Units of insulin per milligram, and

(b) on the dry basis not less than 0·30 per cent and not more than 0·90 per cent zinc, as determined by the official method.[3]

C.03.052. **Insulin** and **Insulin made from Zinc-Insulin Crystals** when prepared for parenteral use[6] shall be a clear, colourless or almost colourless sterile solution free from turbidity and from insoluble matter and shall contain, weight by volume,

(a) not less than 0·1 per cent and not more than 0·25 per cent of either phenol or cresol, and

(b) not less than 1·4 per cent and not more than 1·8 per cent glycerin,

and for each 1,000 International Units of insulin, as determined by the official method,[3]

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[1] See page 1, A.01.010 (*e*) (*i*), C.01.006.
[2] See page 1.
[3] See A.01.010 (*h*).
[4] See C.03.001 (*c*).
[5] See C.01.001 (*c*).
[6] See C.01.001 (*g*).

93, December 28, 1956.
Replaces page 93, September 6, 1956.

(c) not more than 7·0 milligrams of nitrogen for insulin made from zinc-insulin crystals, and not more than 8·5 milligrams of nitrogen for insulin other than that made from zinc-insulin crystals,

(d) not less than 0·10 milligram and not more than 0·40 milligram of zinc for insulin made from zinc-insulin crystals and not more than 0·40 milligram of zinc for insulin other than that made from zinc-insulin crystals, and

(e) in the case of insulin, not more than 1·0 milligram of ash,

and shall have a pH of not less than 2·5 and not more than 3·5.

C.03.053. The unit of potency of insulin or of insulin made from zinc-insulin crystals shall be the International Unit.

C.03.054. **Globin Insulin with Zinc** shall be a sterile solution of insulin modified by the addition of globin prepared from beef blood, in the form of globin hydrochloride, and zinc, and shall be a clear, colourless or almost colourless liquid free from insoluble matter and acceptably free from turbidity, and shall contain, weight by volume,

(a) not less than 1·3 per cent and not more than 1·7 per cent glycerin,

(b) either

(i) not less than 0·15 per cent and not more than 0·20 per cent cresol, or

(ii) not less than 0·20 per cent and not more than 0·26 per cent phenol,

and for each 1,000 International Units of insulin, as determined by the official method,[1]

(c) not more than 15·0 milligrams of total nitrogen,

(d) not less than 36·0 milligrams and not more than 40·0 milligrams of globin calculated as 6·0 times the nitrogen content of the globin, and

(e) not less than 2·5 milligrams and not more than 3·5 milligrams of zinc,

and shall have a pH of not less than 3·4 and not more than 3·8.

C.03.055. The globin hydrochloride used in preparation globin insulin with zinc shall contain not less than 16·0 per cent and not more than 17·5 per cent nitrogen calculated on a dry, ash-free, and hydrochloric acid-free basis, and the ash content shall be not more than 0·3 per cent as determined by the official method.[1]

C.03.056. **Insulin zinc suspension** shall be a sterile suspension, in a buffered aqueous medium, of insulin modified by the addition of zinc, and approximately 70 per cent of the suspension of insulin shall be in a crystalline form and the remainder shall be in an amorphous form, and shall contain weight by volume,

(a) not less than 0·15 per cent and not more than 0·17 per cent of sodium acetate,

(b) not less than 0·65 per cent and not more than 0·75 per cent of sodium chloride,

(c) not less than 0·09 per cent and not more than 0·11 per cent of methyl-*p*-hydroxybenzoate,

and for each 1,000 International Units of insulin as determined by the official method,[1]

(d) not more than 7·0 milligrams of nitrogen of which not less than 55 per cent nor more than 67 per cent is in the crystalline component,

(e) not less than 2·0 milligrams and not more than 2·5 milligrams of zinc, of which not less than 40 per cent and not more than 65 per cent is in the supernatant liquid,

and shall have a pH of not less than 7·1 and not more than 7·5.

C.03.057. The protamine used in preparing NPH insulin and protamine zinc insulin shall be obtained from the sperm or from the mature testes of fish belonging to the family *Salmonidae*, genera *Oncorhynchus* Suckley, or *Salmo* Linne.

C.03.058. **NPH Insulin, Isophane Insulin,** shall be a sterile preparation of crystals containing insulin, protamine and zinc, suspended in a buffered medium, and shall be a white suspension of rod-shaped crystals and shall contain, weight by volume,

(a) not less than 0·15 per cent and not more than 0·25 per cent anhydrous di-sodium phosphate,

(b) either

[1] See A.01.010 (*h*).

(i) not less than 1·4 per cent and not more than 1·8 per cent glycerin and not less than 0·15 per cent and not more than 0·17 per cent metacresol and not less than 0·06 per cent and not more than 0·07 per cent phenol, or

(ii) not less than 0·42 per cent and not more than 0·45 per cent sodium chloride and not less than 0·7 per cent and not more than 0·9 per cent glycerin and not less than 0·18 per cent and not more than 0·22 per cent meta-cresol,

and for each 1,000 International Units of insulin, as determined by the official method,[1]

(c) not more than 8·5 milligrams of nitrogen,

(d) not less than 3·0 milligrams and not more than 6·0 milligrams of protamine provided that the ratio of the protamine to the insulin shall be not less than the isophane ratio nor shall it exceed the isophane ratio by more than 10 per cent, and

(e) not less than 0·16 milligram and not more than 0·40 milligram of zinc,

and shall have a pH of not less than 7·1 and not more than 7·4.

C.03.059. The isophane ratio means the minimum number of milligrams of the protamine required to precipitate 100 International Units of the insulin and shall be determined by an acceptable method.[2]

C.03.060. **Protamine Zinc Insulin** shall be a sterile white suspension containing insulin modified by the addition of protamine and zinc and shall be free from large particles following moderate agitation and shall contain, weight by volume,

(a) not less than 0·15 per cent and not more than 0·25 per cent anhydrous di-sodium phosphate,

(b) not less than 1·4 per cent and not more than 1·8 per cent glycerin,

(c) either

(i) not less than 0·18 per cent and not more than 0·22 per cent cresol, or

(ii) not less than 0·22 per cent and not more than 0·28 per cent phenol,

and for each 1,000 International Units of insulin, as determined by the official method,[1]

(d) not more than 12·5 milligrams of total nitrogen,

(e) not less than 10·0 milligrams and not more than 15·0 milligrams of protamine, and

(f) not less than 2·0 milligrams and not more than 2·5 milligrams of zinc,

and shall have a pH of not less than 7·1 and not more than 7·4.

C.03.061. The insulin used in the preparation of globin insulin with zinc, insulin zinc suspension, NPH insulin, and protamine zinc insulin shall be obtained from one or more master lots and shall be present in an amount sufficient to provide either 40 or 80 International Units of insulin for each cubic centimetre of the preparation.

C.03.062. The clear supernatant liquid obtained from insulin zinc suspension, NPH insulin and from protamine zinc insulin by centrifuging or by filtering shall contain not more than 1 International Unit of insulin per cubic centimetre when the potency of the insulin preparation is 40 units per cubic centimetre, and not more than 1·5 International Units of insulin per cubic centimetre when the potency of the insulin preparation is 80 units per cubic centimetre, as determined by the official method.[1]

C.03.063. The Canadian Reference Standards for insulin and insulin made from zinc-insulin crystals, globin insulin with zinc, and protamine zinc insulin mean standards adopted by the Director[3] from whom portions and directions for comparative testing may be had upon application.

C.03.064. The biological reaction of globin insulin with zinc, and of protamine zinc insulin shall be comparable to that of the respective Canadian Reference Standard as determined by an acceptable method.[2]

C.03.065. The potency of insulin, insulin made from zinc-insulin crystals, globin insulin with zinc, insulin zinc suspension, NPH insulin or protamine zinc insulin shall be expressed in units per cubic centimetre.

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[1] See A.01.010 *(k)*.
[2] See A.01.010 *(a)*.
[3] See A.01.010 *(d)*.

95, December 28, 1956.
Replaces page 95.

C.03.066. Insulin, and insulin made from zinc-insulin crystals shall not be dispensed except

(a) in vials of approximately 10 cubic centimetre capacity that shall contain an excess volume sufficient to permit withdrawal of 10 cubic centimetres, and

(b) each cubic centimetre thereof shall provide

(i) 40 International Units of insulin, or

(ii) 80 International Units of insulin, or

(iii) 100 International Units of insulin.

C.03.067. Globin insulin with zinc, insulin zinc suspension, NPH insulin, and protamine zinc insulin shall not be dispensed except

(a) in vials of approximately 10 cubic centimetre capacity that shall contain an excess volume sufficient to permit withdrawal of 10 cubic centimetres, and

(b) each cubic centimetre thereof shall provide

(i) 40 International Units of insulin, or

(ii) 80 International Units of insulin.

C.03.068. The potency of insulin, or of insulin made from zinc-insulin crystals, as determined by the official method,[1] shall be not less than 95 per cent and not more than 105 per cent of that stated on the label.[2]

C.03.069. Both the inner and the outer labels[2] of every package of each strength of the insulin preparation shall be printed as follows:

(a) insulin, in

(i) black ink on yellow coloured stock for 40 units per cubic centimetre,

(ii) black ink on green coloured stock for 80 units per cubic centimetre, and

(iii) black ink on red coloured stock for 100 units per cubic centimetre,

(b) insulin made from zinc-insulin crystals, in

(i) red ink on grey coloured stock for 40 units per cubic centimetre, and

(ii) green ink on grey coloured stock for 80 units per cubic centimetre,

(c) globin insulin with zinc, in

(i) red ink on brown coloured stock for 40 units per cubic centimetre except that the expression *40 units per cubic centimetre* may be printed in white letters on a red background, and

(ii) green ink on brown coloured stock for 80 units per cubic centimetre except that the expression *80 units per cubic centimetre* may be printed in white letters on a green background,

(d) insulin zinc suspension, in

(i) red ink on lavender stock for 40 units per cubic centimetre, and

(ii) green ink on lavender stock for 80 units per cubic centimetre,

(e) NPH insulin, in

(i) red ink on blue coloured stock for 40 units per cubic centimetre, and

(ii) green ink on blue coloured stock for 80 units per cubic centimetre, and

(f) protamine zinc insulin, in

(i) red ink on white stock for 40 units per cubic centimetre, and

(ii) green ink on white stock for 80 units per cubic centimetre.

C.03.070. The outer label[2] of every package containing an insulin preparation shall carry an instruction to keep in a cold place and avoid freezing.

C.03.071. The inner label[2] of every package of insulin zinc suspension, NPH insulin and of protamine zinc insulin shall carry the statement "Shake carefully".

C.03.072. Each package of an insulin preparation shall contain a descriptive circular that includes

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[1] See A.01.010 (*h*).
[2] See page 1, A.01.010 (*e*) (*i*), C.01.006.

(a) a statement that treatment of *diabetes mellitus* requires medical supervision and review, and that preparations containing insulin should be used only as determined by a physician for each patient in the light of blood-sugar and urinary-sugar findings, and that the physician's instructions concerning diet, dosage, rest, and exercise should be followed carefully,

(b) an outline of a procedure to be followed in withdrawing the insulin preparation from the vial, including technique for sterilization of syringe and needle, vial-stopper and site of injection,

(c) a statement explaining that injections should be subcutaneous, and not intravenous or intramuscular, and a caution against successive injections in any one site,

(d) a statement that doses are specified in terms of *Units* and that the *volume* of each dose will depend upon the potency in terms of such units per cubic centimetre stated on the label of the product and that for these reasons it is important that the patient understands the markings on syringes,

(e) a brief explanation of *hypoglycaemia* together with emergency measures suitable for use by patients and those caring for patients in the event of hypoglycaemic reactions,

(f) a statement indicating the possibility of undesirable reactions associated with the omission or loss of a meal, illness, infection, and shortage of the insulin preparation,

(g) a statement warning against using any other types of insulin than those prescribed by the physician,

(h) a statement that the use of a package should not be commenced after the expiration date printed on the package,

(i) a statement that the contents should be used as continuously as practicable and that any vial from which a part of the contents has been withdrawn should be discarded in the event of its being in disuse for several weeks' time,

(j) a statement stressing the importance of visiting a physician regularly and carefully following his instructions,

(k) in the case of insulin, insulin made from zinc-insulin crystals, and globin insulin with zinc, a statement that if the contents of the vital become cloudy or turbid, use of that vial should be discontinued, and

(l) in the case of insulin zinc suspension, NPH insulin and protamine zinc insulin, a statement explaining that it is necessary to shake the vial carefully before withdrawing a dose, noting that if the contents have become lumpy or granular in appearance or have formed a deposit of particles on the wall of the container, the use of that vial should be discontinued.

C.03.073. The manufacturer[1] shall submit to the Director,[2] and in each case such submissions shall be acceptable to the Minister,[3]

(a) for each master lot[4] of insulin or zinc-insulin crystals, employed in the manufacture of an insulin preparation

(i) protocols of assay of potency in International Units per cubic centimetre in the case of insulin and in International Units per milligram in the case of zinc-insulin crystals,

(ii) a report of the moisture content in per cent determined by drying to constant weight at 100°C. in the case of zinc-insulin crystals,

and for each 1,000 International Units of insulin, reports of

(iii) the nitrogen content in milligrams, and

(iv) the zinc content in milligrams,

(b) for the master lot of globin hydrochloride used in the preparation of globin insulin with zinc, reports of

(i) the nitrogen content in per cent calculated on a dry, ash-free and hydrochloride acid-free basis,

(ii) the chloride content in per cent calculated as hydrochloride, and

(iii) the ash content in per cent,

(c) for the master lot of protamine, a report of the isophane ratio for the insulin used in the preparation of NPH insulin,

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[1] See A.01.010 (*g*).
[2] See A.01.010 (*d*).
[3] See page 1.
[4] See C.03.001 (*d*).

(d) for the components used in the preparation of the trial mixture of globin insulin with zinc, insulin zinc suspension, and protamine zinc insulin, a report on the quantity of

(i) the insulin in grams, or in International Units,

(ii) the zinc in grams, or in milligrams per 1,000 International Units of insulin,

(iii) in the case of globin insulin with zinc, the globin hydrochloride in grams, or in milligrams per 1,000 International Units of insulin, and

(iv) in the case of protamine zinc insulin, the protamine in grams, or in milligrams per 1,000 International Units of insulin, and

(e) for the trial mixture of globin insulin with zinc, insulin zinc suspension, NPH insulin and protamine zinc insulin, a report of the determination of

(i) the nitrogen content in milligrams per cubic centimetre, or per 1,000 International Units of insulin,

(ii) the zinc content in milligrams per cubic centimetre, or per 1,000 International Units of insulin, and

(iii) the pH,

(f) in addition, for the trial mixture of

(i) globin insulin with zinc and protamine zinc insulin, protocols of the biological reaction showing the retardation of the insulin effect,

(ii) insulin zinc suspension, NPH insulin and protamine zinc insulin, protocols of assay of the insulin content in International Units per cubic centimetre of the supernatant fluid after removal of the suspended precipitate by centrifuging or filtering, and

(iii) insulin zinc suspension and NPH insulin, a report on the microscopic examination of the precipitate,

(g) for the first finished lot of insulin, insulin made from zinc-insulin crystals, globin insulin with zinc, insulin zinc suspension, NPH insulin or protamine zinc insulin from each master lot or trial mixture of the respective insulin preparation, a report on the amount of each component in the preparation, and

(h) for the first filling of the first finished lot of insulin, or insulin made from zinc-insulin crystals, globin insulin with zinc, insulin zinc suspension, NPH insulin, and protamine zinc insulin from each master lot of the respective insulin

(i) a report of the nitrogen content in milligrams per cubic centimetre or 1,000 International Units,

(ii) a report of the zinc content in milligrams per cubic centimetre or 1,000 International Units,

(iii) a report of the pH,

(iv) at least 6 vials taken by random sampling, and

(v) in addition in the case of insulin zinc suspension and NPH insulin, reports on the microscopic examination of the precipitate, and on the identification as determined by an acceptable method.[1]

C.03.074. Insulin from a master lot,[2] or insulin made from zinc-insulin crystals from a fluid master lot, shall be stored at a temperature between 0°C. and 15°C.

C.03.075. Notwithstanding C.03.066 *(a)* and *(b)*, C.03.068, C.03.069 *(a)* and *(b)*, and C.03.073 *(h)* (iv), *Insulin made from Zinc-Insulin Crystals* 500 International Units per cubic centimetre may be sold provided that

(a) it is dispensed in vials of approximately 20 cubic centimetre capacity that shall contain an excess volume sufficient to permit withdrawal of 20 cubic centimetres,

(b) both the inner and the outer labels[3] are printed in black ink on white stock and overprinted in narrow brown and white diagonal stripes, of which there shall be at least five but not more than 20 to each inch,

(c) both the inner and the outer labels[3] carry the statement "Warning—High Potency—Not for Ordinary Use", and

(d) each package contains a descriptive circular that includes

(i) at the beginning of the circular the statement "Warning—This insulin preparation contains 500 International Units of insulin in each cubic centimetre. Extreme caution

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[1] See A.01.010 *(a)*.
[2] See C.03.001 *(d)*.
[3] See page 1, A.01.010 *(e)* *(i)*, C.01.006.

must be observed in the measurement of the doses because inadvertent over-dose may result in irreversible shock. Serious consequences may result if it is used other than under constant medical supervision. Unless specifically prescribed, it should never be used by patients to replace use of any other insulin preparation",

(ii) a statement that *Insulin made from Zinc-Insulin Crystals* 500 International Units per cubic centimetre should not be administered intravenously,

(iii) a statement giving information for the safe and effective use by physicians of the drug in insulin shock therapy and in the treatment of diabetic patients with high insulin resistance (daily requirement more than 200 International Units),

(iv) a statement that this preparation should not be used after the expiration date shown on the outer label, and

(v) a statement that this preparation should not be used if the solution becomes viscous, discoloured, or other than water-clear.

C.03.076. The expiration date[1] printed on the outer label[2] of every package of

(a) insulin and of insulin made from zinc-insulin crystals shall be not later than two years after the date of removal for distribution from the manufacturer's place of storage,

(b) insulin zinc suspension, NPH insulin, and globin insulin with zinc shall be not later than 18 months after the date of filling of the immediate container, and

(c) protamine zinc insulin shall be not later than two years after the date of filling of the immediate container.

Anterior Pituitary Extracts

C.03.175. Anterior pituitary extract shall include all natural products, prepared from the anterior lobe of the pituitary gland of animals, having physiological properties associated with the hormones of the anterior pituitary gland and their proper names[3] shall be

(a) **Adrenocorticotrophic Hormone, Corticotrophin,**

(b) **Thyrotrophic Hormone, Thyrotrophin,**

(c) **Growth Hormone Pituitary, Somatotrophin,**

(d) **Lactogenic Hormone, Prolactin,**

(e) **Gonadotrophic Hormone, Gonadotrophin,** followed by qualifying words to indicate the gonadotrophic activity associated with the extract,

and if unpurified anterior pituitary extract

(f) **Pituitary Extract Anterior Lobe** followed by qualifying words to indicate the physiological properties associated with it.

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[1] See C.01.001 (*c*).
[2] See page 1, A.01.010 (*e*) (*i*), C.01.006.
[3] See C.01.001 (*k*).

C.03.176. Reference standards for anterior pituitary extract shall be

(a) the International Standard,

(b) where no International Standard exists, the Canadian Reference Standard shall be that established and kept by the Director from whom portions for comparative testing may be had upon application, and

(c) where neither an International Standard nor a Canadian Reference Standard exists, a provisional reference standard that shall be a suitable quantity of the product submitted by the manufacturer to the Director for checking the uniformity of the product.

C.03.177. Both the inner and the outer labels[1] of an anterior pituitary extract shall carry a statement of the potency in terms of the reference standard for anterior pituitary extract provided in C.03.176 as determined by an acceptable method,[2] except that where no reference standard for an anterior pituitary extract exists, the manufacturer[3] shall include, with every package of the anterior pituitary extract an acceptable statement of the unit of potency and the method of assay used.

C.03.178. No person shall sell[4] adrenocorticotrophic hormone for

(a) subcutaneous or intramuscular use, unless the preparation has been assayed by an acceptable method[2] involving subcutaneous injection,

(b) intravenous use only, unless the preparation has been assayed by an acceptable method[2] involving intravenous injection,

(c) intranasal use by inhalation, unless the preparation has been assayed by an acceptable method[2] involving intravenous injection, or

(d) either intramuscular, subcutaneous or intravenous use, unless the ratio of the activity found by assay involving subcutaneous injection and that found by assay involving intravenous injection is not less than 0·80 and not more than 1·25.

C.03.179. No person shall sell[4] as such adrenocorticotrophic hormone, thyrotrophic hormone, growth hormone pituitary, lactogenic hormone, or gonadotrophic hormone that is not acceptably free from any anterior pituitary extract other than the one for which it is named.

C.03.180. The outer label[1] of a mixture of two or more of adrenocorticotrophic hormone, thyrotrophic hormone, growth hormone pituitary, lactogenic hormone, or gonadotrophic hormone or a mixture of any of these with pituitary extract anterior lobe shall carry a declaration of the name and the amount of each component of the mixture.

C.03.181. The outer label[1] of an anterior pituitary extract or mixture of anterior pituitary extracts shall carry a statement

(a) showing the species of animal from which the glands used in the preparation of the anterior pituitary extract were obtained,

(b) that it shall be stored at refrigerator temperature, and

(c) that it is to be used only on the advice or on the prescription of a physician except in the case of adrenocorticotrophic hormone.

C.03.182. Both the inner and the outer labels[1] of adrenocorticotrophic hormone shall carry a statement indicating the route of administration, in addition to meeting the requirements of C.03.181 *(a)* and *(b)*.

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[1] See page 1, A.01.010 (*e*) (*i*), C.01.006.
[2] See A.01.010 (*a*).
[3] See C.03.001 (*c*).
[4] See page 1.

C.03.183. The expiration date[1] for an anterior pituitary extract or mixture of anterior pituitary extracts shall be not more than two years after the date of passing a potency test.

Radioactive Isotopes

C.03.201. Radioactive isotopes shall include all substances having the property of emitting alpha or beta particles or gamma rays, and their proper names[2] shall be the name of the respective atom showing its mass number and the compound in which it is combined.

C.03.202. The unit of activity of radioactive isotopes shall be expressed in terms of the International curie.

C.03.203. Both the inner and the outer labels[3] of radioactive isotopes shall carry

(a) a statement of the activity in International curies, and

(b) a statement of the date when the labelled activity was measured.

C.03.204. No person shall ship radioactive isotopes unless they are packaged in such a manner that the hazard of handling is sufficiently reduced to satisfy the standards required by the regulations of the Board of Transport Commissioners.

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[1] See C.01.001 (*c*).
[2] See C.01.001 (*k*).
[3] See page 1, A.01.010 (*e*) (*i*), C.01.006.

99A, September 6, 1956.
Replaces page 99A.

Schedule D[1] Drugs

C.04.001. In this DIVISION

(a) "date of manufacture" means

(i) in the case of a product for which a standard of potency exists, the date it satisfactorily passes a potency test,

(ii) in the case of an animal product for which no standard of potency exists, the date of its removal from the animal, and

(iii) in the case of a product other than an animal product for which no standard of potency exists, the date of cessation of growth,

(b) "drug" means any drug mentioned or described in SCHEDULE D to the Act,

(c) "licence" or "Canadian licence" means the prescribed form and manner used by the Minister to indicate that the premises in which a drug was in whole or in part manufactured, and the process and conditions of manufacture therein are suitable to ensure that the drug is not unsafe for use, and

(d) "manufacturer" means a person to whom a licence has been issued as provided in this DIVISION.

C.04.002. This DIVISION does not apply to a drug labelled for veterinary use only.

C.04.003. The date of issue of a drug shall be the date on which the finished product is removed from cold storage but in any case shall be, not later than

(a) 6 months after the date of manufacture for a drug that has been kept constantly at a temperature not exceeding 10°C.,

(b) 12 months after the date of manufacture for a drug that has been kept constantly at a temperature not exceeding 5°C., or

(c) two years after the date of manufacture for a drug that has been kept constantly at a temperature not exceeding 0°C.

C.04.004. An application for a licence[2] and for the renewal thereof shall be made on the form prescribed therefor in Appendix III[3] and shall be accompanied by a fee of ten dollars payable to the Receiver General of Canada.

C.04.005. As a condition of the issuance and continuation of a licence,[2] the Minister may require

(a) inspection to be made at any time during normal business hours of

(i) the premises in which a drug, which is the subject of an application, is manufactured, and the process and conditions of manufacture therein,

(ii) the qualifications of technical staff concerned with the manufacture of the drug, and

(iii) the records relevant to the drug,

(b) that the manufacturer[4] shall supply, on request of the Minister, samples of any material used in the production of the drug and samples of the finished drug

to ensure that the drug will not be unsafe for use.

C.04.006. As a condition of the issuance and continuation of a licence,[2] the Minister may require a manufacturer[4] who manufactures a drug outside Canada under a Canadian licence[2]

(a) to designate a representative in Canada,

(b) to furnish the name and address of such representative who shall maintain satisfactory records of the distribution of the drug in Canada.

C.04.007. A licence[2] shall be in the form prescribed therefor in Appendix III[3] and shall expire on the 31st of March of each year.

C.04.008. The Minister may make a charge to cover the necessary living and travelling expenses of any inspector in connection with any inspection as required by these regulations.

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[1] See page 10.
[2] See C.04.001 (*c*).
[3] See page 142.
[4] See C.04.001 (*d*).

C.04.009. The Minister may refuse to issue a licence,[1] or may cancel, or may suspend any licence so issued in whole, or as regards to any drug in respect of which it is issued, and may impose such conditions for the removal of such suspension or the reinstatement of the licence as he considers necessary to ensure that any drug for which the licence is issued will not be unsafe for use.

C.04.010. Every manufacturer[2] shall keep records in a satisfactory form respecting the manufacture, testing, and distribution of each lot of a drug manufactured by him, giving the date of such manufacture, testing or distribution, and make these records available to the Minister on request.

C.04.011. The Minister may refuse to issue, or may cancel or suspend the licence of a manufacturer[2] who does not maintain his premises under the direct control and personal super, vision of a responsible, qualified person.

C.04.012. A manufacturer[2] shall notify the Minister promptly of changes in

(a) responsible qualified personnel,

(b) premises in which the drug is manufactured, and

(c) process and conditions of manufacture therein.

C.04.013. A manufacturer[2] shall safely segregate all work with spore-bearing, pathogenic micro-organisms and other infectious agents known to require special precautions in manipulation and shall take such care of equipment and arrangements for supervision that the possibility of contamination of other drugs is avoided.

C.04.014. No manufacturer[2] shall conduct laboratory procedures of a diagnostic nature in his premises unless such procedures are entirely segregated from the production of drugs.

C.04.015. Upon written request from the Director a manufacturer shall submit protocols of tests together with samples of any lot of any drug prior to its being sold, and no person shall sell any lot of which the protocol or sample fails to meet the requirements of these regulations.

C.04.016. All animals from which drugs are produced shall be

(a) under the direct supervision of competent medical or veterinary personnel,

(b) kept in quarantine by the manufacturer for at least seven days before use, and

(c) healthy and free from infectious disease.

C.04.017. A manufacturer[2] shall keep necropsy records of all animals that die or are killed after having been used in the production of a drug.

C.04.018. A manufacturer[2] shall immediately segregate, and report the fact to the Minister, any animal with actual or suspected vesicular stomatitis, foot and mouth disease, encephalomyelitis, infectious anaemia, glanders, anthrax, tetanus or any other serious infectious disease.

C.04.019. The provisions of C.01.004 do not apply to a drug as defined in this DIVISION but every package of such drug shall carry

(a) on both the inner and the outer labels[3]

(i) the proper name of the drug as specified in the licence, and where there is a proprietary or brand name the proper name shall immediately precede or follow the said proprietary or brand name in type of not less than one-half the size thereof,

(ii) the name of the manufacturer,[2]

(iii) the potency of the drug, where applicable,

(iv) the recommended dose of the drug,

(v) the lot number,[4]

(vi) the expiration[4] date except upon the inner label of a single-dose container,

(vii) adequate directions for use, and

(b) on the outer label[5]

(i) the address of the manufacturer,[2]

(ii) the Canadian licence[1] number of the manufacturer,[2]

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[1] See C.04.001 (*c*).
[2] See C.04.001 (*d*).
[3] See page 1, A.01.010 (*e*) (*i*), C.01.006.
[4] The lot number should be preceded by the words "Lot Number" or by "Lot No.", "Lot" or "(L.)".
[5] See C.01.001 (*e*).

(iii) the name and amount of any preservative in the drug,
(iv) a statement that the drug shall be stored at a temperature of not less than 2°C. and not more than 10°C., and
(v) a statement of the net contents in terms of weight, measure, or number.

Bacterial Vaccines, Products Analogous to Bacterial Vaccines

C.04.050. Except as provided in this DIVISION, a bacterial vaccine shall be a sterile suspension of killed cultures of bacteria, with or without the addition of other medication, and shall not include an autogenous vaccine.

C.04.051. No person shall sell a bacterial vaccine unless the culture that has been used in its preparation has been tested by an acceptable method[1] for identity and purity and when so tested it shall be true to name and a pure strain, and a record of the culture shall be maintained which shall include a statement of its origin, properties and characteristics.

C.04.052. No manufacturer[2] shall use a substrate (culture medium), in the production of a bacterial vaccine, that contains any horse meat or horse serum.

C.04.053. A manufacturer[2] of a bacterial vaccine prepared from a bacterium that does not grow readily in ordinary culture media shall test its sterility in media which are specially favourable to the growth of such bacterium, and it shall be sterile.

C.04.054. Except as provided in C.04.083 and C.04.090, both the inner and the outer labels[3] of every multiple-dose container and the outer label[3] of every single-dose container of a bacterial vaccine shall carry a statement of

(a) the number of bacteria per millilitre, or the weight of dried substance of bacteria per millilitre,

(b) the number of bacteria per millilitre, or the weight of dried substance of bacteria per millilitre, of each species or immunogenic type for a vaccine that contains a number of different species or immunogenic types of bacteria,

(c) the exact nature and amount of any substance, other than a simple diluent, combined with such vaccine and

(d) the recommended dose,

and the inner label[3] of a single-dose container shall carry a statement that it contains only one dose.

C.04.055. The expiration date[4] of a bacterial vaccine shall be not later than 18 months after the date of manufacture[5] or the date of issue.[6]

Typhoid Vaccine

C.04.060. Cultures of *Salmonella typhosa* used in the preparation of typhoid vaccine shall be smooth, motile, and in the Vi form, with the following antigenic structure IX, XII, Vi; d.-.

C.04.061. No person shall sell any lot of typhoid vaccine unless such lot has been shown to meet a test for potency made by an acceptable method.[1]

Whooping Cough Vaccine

C.04.065. A manufacturer shall use only strains of *Haemophilus pertussis* that meet the requirements of an antigenic test made by an acceptable method[1] for the preparation of whooping cough (pertussis) vaccine.

C.04.066. No person shall sell[7] any lot of whooping cough (pertussis) vaccine unless such lot has been shown to meet a test for potency made by an acceptable method.[1]

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[1] See A.01.010 (*a*).
[2] See C.04.001 (*d*).
[3] See page 1, A.01.010 (*e*) (*i*), C.01.006
[4] See C.01.001 (*c*).
[5] See C.04.001 (*a*).
[6] See C.04.003.
[7] See page 1.

B.C.G. (Bacille Calmette-Guerin) Vaccine

C.04.070. B.C.G. Vaccine shall be prepared from living B.C.G. organisms that

(a) have been obtained directly from a source approved by the Director,

(b) are proved to be non-pathogenic by an acceptable method,[1] and

(c) have a history of successful use in the production of B.C.G. vaccine.

C.04.071. No manufacturer[2] shall employ any person in the manufacture of B.C.G. vaccine unless such person

(a) has been and remains free from all forms of tuberculous infection,

(b) undergoes every 6 months a medical examination, that shall include an X-ray examination of the chest, for the presence of tuberculosis, such examination being made by a qualified, practising physician who shall sign a certificate of such person's freedom from tuberculosis, and such certificate shall be kept on file and be available at all times, and

(c) resides in a household that is at all times free from active tuberculosis,

nor shall a manufacturer employ such person in any other laboratory position.

C.04.072. The manufacture of B.C.G. vaccine shall be under the direct supervision of an experienced, medically qualified bacteriologist who has graduated in medicine from a university of recognized standing and who has

(a) not less than three years postgraduate training in bacteriology and immunology,

(b) specialized in the field of bacteriology, and

(c) at least one year of practical experience in the manufacture of B.C.G. vaccine.

C.04.073. No manufacturer[2] shall permit any culture that is not a B.C.G. culture to be at any time on any premises that are used for the manufacture of B.C.G. vaccine.

C.04.074. A manufacturer[2] shall test by an acceptable method,[1] immediately after filling of the final container, each lot of B.C.G. vaccine for the presence of contaminating micro-organisms and when so tested it shall be free therefrom.

C.04.075. Notwithstanding C.04.074 a fluid B.C.G. vaccine may be released for sale if no growth has appeared upon the test culture medium after an incubation of 24 hours, but if there is evidence of the presence of contaminating micro-organisms in any lot during the test period of 10 days the manufacturer[2] shall at once recall such lot.

C.04.076. A manufacturer shall determine the number of viable B.C.G. organisms in each lot of vaccine by an acceptable method[1] and shall keep a record of the number.

C.04.077. A manufacturer[2] of B.C.G. vaccine shall keep, at a temperature not exceeding 5·0°C., and for not less than 6 months,

(a) the culture on glycerine-water potato medium from which the Sauton I and Sauton II subcultures were made, and

(b) not less than six vials of the final product

from each lot thereof.

C.04.078. A manufacturer[2] of B.C.G. vaccine shall keep, in form satisfactory to the Minister, continuous clinical records of the use of B.C.G. vaccine in humans.

C.04.079. A manufacturer[2] of B.C.G. vaccine shall examine pathologically all test animals used and shall immediately report to the Minister any evidence of active, progressive tuberculosis in any such animals.

C.04.080. Notwithstanding C.04.055 the expiration date[3] for fluid B.C.G. vaccine shall be not more than 10 days after harvesting.

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[1] See A.01.010 (*a*).
[2] See C.04.001 (*d*).
[3] See C.01.001 (*c*).

C.04.081. No person shall sell[1] fluid B.C.G. vaccine that is not packaged in containers sealed by fusion.

C.04.082. No inner label[2] shall be required for B.C.G. vaccine in single-dose containers.

C.04.083. The label[2] of B.C.G. vaccine shall carry, in lieu of the statements provided in C.04.054 *(a)* and *(b)*, a statement of

(a) the weight of bacteria per millilitre, and

(b) the route of administration of the vaccine.

Products Analogous to Bacterial Vaccines

C.04.090. A product analogous to a bacterial vaccine shall be

(a) a bacterial antigen, other than a bacterial vaccine, such as a lysate, or

(b) an extract prepared from a bacterial culture,

and shall conform to the requirements of these regulations for bacterial vaccines except those of paragraphs *(a)* and *(b)* of C.04.054.

C.04.091. The expiration date[3] of a product analogous to a bacterial vaccine shall be not later than 18 months after the date of manufacture[4] or the date of issue,[5] but for dried tuberculin and tuberculin containing at least 50 per cent glycerin the expiration date shall be not later than five years after the date of manufacture or the date of issue, and for all other tuberculins not more than 12 months after the date of manufacture or the date of issue.

Virus and Rickettsial Vaccines

C.04.100. A virus vaccine, rickettsial vaccine, shall be a suspension of, or prepared from, living or killed viruses or rickettsiae.

C.04.101. A manufacturer[6] shall submit to the Minister for his approval at the time application for a licence is made to manufacture a virus or rickettsial vaccine details of the source of the strains of viruses or rickettsiae used, the method of their propagation, the method of manufacture of the vaccine, and the methods employed for determining sterility, safety, identity, potency, and any other tests required by these regulations.

C.04.102. Upon written request from the Director a manufacturer[6] shall submit with respect to each lot of virus or rickettsial vaccine, when ready for sale, detailed protocols of sterility, safety, identity, potency, and of any other tests required by these regulations.

Smallpox Vaccine

C.04.110. Smallpox vaccine shall be a virus vaccine and shall be the living virus of vaccinia obtained from the vesicles produced in the skin of healthy calves by inoculation of vaccinia virus.

C.04.111. A manufacturer[6] shall manufacture smallpox vaccine only in an independent unit that is so designed as to afford strict isolation from all other laboratory activities and in or about which no extraneous materials shall be permitted or stored.

C.04.112. A manufacturer[6] shall exclude the personnel, who care for the vaccine animals, from horse stables and paddocks and from contact with horses while smallpox vaccine is being propagated.

C.04.113. A manufacturer[6] shall dispense smallpox vaccine only in sterile glass containers that are sealed under aseptic conditions.

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[1] See page 1.
[2] See page 1, A.01.010 *(e)* *(i)*, C.01.006.
[3] See C.01.001 *(c)*.
[4] See C.04.001 *(a)*.
[5] See C.04.003.
[6] See C.04.001 *(d)*.

C.04.114. A manufacturer[1] shall test smallpox vaccine for the presence of any gas-producing spore-forming anaerobic organism, of any coagulase positive staphylococci, of any haemolytic streptococcus and it shall be free therefrom.

C.04.115. Smallpox vaccine shall not contain more than 500 viable non-pathogenic bacteria per millilitre when tested by an acceptable method.[2]

C.04.116. Smallpox vaccine shall produce a confluent take when 0·05 millilitre of a 1 in 500 dilution is spread over 2 square inches of the scarified skin of a normal rabbit.

C.04.117. No person shall sell[3] smallpox vaccine unless the outer label[4] carries a statement that it shall be stored at a temperature of not more than 5°C.

C.04.118. The expiration date[5] of smallpox vaccine shall be not later than 3 months after the date of manufacture[6] or the date of issue.[7]

C.04.119. Notwithstanding the provisions of C.04.003 the date of issue[7] of smallpox vaccine shall be not later than 9 months after the date of manufacture[6] where the vaccine has been stored at a temperature below 0°C.

C.04.120. No inner label[4] shall be required for smallpox vaccine in single-dose containers or when dispensed in capillary tubes.

C.04.121. No person shall sell[3] smallpox vaccine to which an antibiotic[8] has been added.

Bacteriophage

C.04.130. Bacteriophage shall be a virus preparation with specific lytic action against micro-organisms actually or potentially pathogenic.

C.04.131. The expiration date[5] of bacteriophage shall be not later than 12 months after the date of manufacture[6] or the date of issue.[7]

Toxins, Toxoids

Schick Test Reagents

C.04.140. Schick test reagents for the diagnosis of susceptibility to diphtheria shall be

(a) diphtheria toxin for Schick test,

(b) Schick control, and

(c) diphtheria toxin for Schick test with control.

C.04.141. Diphtheria toxin for Schick test shall be sterile diluted diphtheria toxin stabilized by an acceptable method.[2]

C.04.142. Schick control shall be suitably diluted

(a) diphtheria toxoid, or

(b) sterile diphtheria toxin heated at a temperature of 95°C. for 5 minutes.

C.04.143. The human test dose of diphtheria toxin for Schick test, when aged toxin containing a preservative is used, shall be determined by

(a) intracutaneous injection into normal guinea pigs in mixtures with different proportions of diphtheria antitoxin, and one test dose mixed with 1/750 or more of a unit of antitoxin must cause no local reaction but mixed with 1/1250 or less of a unit of antitoxin must

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[1] See C.04.001 (*d*).
[2] See A.01.010 (*a*).
[3] See page 1.
[4] See page 1, A.01.010 (*e*) (*i*), C.01.006.
[5] See C.01.001 (*c*).
[6] See C.04.001 (*a*).
[7] See C.04.003.
[8] See C.01.001 (*a*).

cause a definite local reaction of the type known as the "positive Schick reaction", and

b) intracutaneous injection into normal guinea pigs without admixture with antitoxin, and 1/50 of one test dose must not cause, and 1/25 of one test dose must cause, a definite local reaction of the type known as the "positive Schick reaction".

C.04.144. The human test dose of diphtheria toxin for Schick test, when fresh toxin containing no preservative is used, shall be determined by

a) intracutaneous injection into normal guinea pigs in mixtures with different proportions of diphtheria antitoxin, and one test dose mixed with 1/750 or more of a unit of antitoxin must cause no local reaction, but mixed with 1/1500 or less of a unit of antitoxin must cause a definite local reaction of the type known as the "positive Schick reaction", and

b) intracutaneous injection into normal guinea pigs without admixture with antitoxin, and 1/100 of one test dose must not cause, and 1/50 of one test dose must cause, a definite local reaction of the type known as the "positive Schick reaction".

C.04.145. The human test dose for the Schick control shall give a negative Schick reaction when injected intracutaneously into normal guinea pigs.

C.04.146. No person shall sell[1] diphtheria toxin for Schick test unless both the inner and the outer labels[2] carry a statement of the number of human test doses it contains together with the name of any stabilizer.

C.04.147. The expiration date[3] of Schick test reagents for the diagnosis of susceptibility to diphtheria shall be not later than 12 months after the date of manufacture[4] or the date of issue.[5]

Diphtheria Toxoid

C.04.160. Liquid diphtheria toxoid shall be sterile, formalized, detoxified diphtheria toxin and shall not contain more than 0·02 per cent free formaldehyde.

C.04.161. Diphtheria toxoid alum precipitated shall be prepared from diphtheria toxoid, and shall not contain more than 15 milligrams of alum per human dose.

C.04.162. The alum used in the preparation of diphtheria toxoid alum precipitated shall contain not less than 99·5 per cent pure potassium alum, $Al\ K(SO_4)_2,\ 12H_2O$.

C.04.163. No manufacturer[6] shall use a culture medium for the production of diphtheria toxin that contains horse protein or Witte peptone or that has not been freed as far as possible from any other allergenic ingredient.

C.04.164. Diphtheria toxin from which diphtheria toxoid is prepared shall have a toxicity, as indicated by an L+ dose, of not more than 0·20 millilitre or by an M.L.D. of not more than 0·0025 millilitre.

C.04.165. A manufacturer[6] shall test each bulk container of diphtheria toxoid, before being dispensed into the final containers, for toxicity by an acceptable method,[7] and it shall be non-toxic.

C.04.166. No person shall sell[1] any lot of diphtheria toxoid unless such lot has been shown to meet a test for antigenicity made by an acceptable method.[7]

C.04.167. A manufacturer[6] shall fill diphtheria toxoid aseptically into clear glass containers and where preservative is not added shall seal the containers by fusion.

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[1] See page 1.
[2] See page 1, A.01.010 (*e*) (*i*), C.01.006.
[3] See C.01.001 (*c*).
[4] See C.04.001 (*c*).
[5] See C.04.003.
[6] See C.04.001 (*d*)
[7] See A.01.010 (*a*).

C.04.168. No person shall sell[1] diphtheria toxoid that contains phenol.

C.04.169. No person shall sell[1] diphtheria toxoid unless both the inner and the outer labels[2] carry a statement of the appropriate dose for purposes of immunization.

C.04.170. The expiration date[3] of diphtheria toxoid shall be not later than two years after the date of manufacture[4] or the date of issue.[5]

Tetanus Toxoid

C.04.180. Liquid tetanus toxoid shall be sterile, formalized, detoxified tetanus toxin, and shall not contain more than 0·02 per cent free formaldehyde.

C.04.181. Tetanus toxoid alum precipitated shall be prepared from tetanus toxoid, and shall not contain more than 15 milligrams of alum per human dose.

C.04.182. The alum used in the preparation of tetanus toxoid alum precipitated shall contain not less than 99·5 per cent pure potassium alum, $Al\ K(SO_4)_2,\ 12H_2O$.

C.04.183. No manufacturer[6] shall use a culture medium for the production of tetanus toxin that contains horse protein or Witte peptone or that has not been freed as far as possible from any other allergenic ingredient.

C.04.184. Tetanus toxin from which tetanus toxoid is prepared shall have a toxicity as indicated by an M.L.D. for the guinea pig of not more than 0·0001 millilitre.

C.04.185. A manufacturer[6] shall test each bulk container of tetanus toxoid, before being dispensed into the final containers, for toxicity by an acceptable method,[7] and it shall be non-toxic.

C.04.186. No person shall sell[1] any lot of tetanus toxoid unless such lot has been shown to meet a test for antigenicity made by an acceptable method.[7]

C.04.187. No person shall sell[1] tetanus toxoid unless both the inner and the outer labels[2] carry a statement of the appropriate dose for purposes of immunization.

C.04.188. A manufacturer[6] shall fill tetanus toxoid aseptically into clear glass containers and where a preservative is not added shall seal the container by fusion.

C.04.189. No person shall sell[1] tetanus toxoid that contains phenol.

C.04.190. The expiration date[3] of tetanus toxoid shall be not later than two years after the date of manufacture[4] or the date of issue.[5]

Antitoxins, Antisera

C.04.210. An antitoxin or antiserum shall be the serum or fraction thereof separated from the blood of animals that have been artificially immunized against the by-products or antigenic fractions of specific cultures of micro-organisms, or against specific venoms.

C.04.211. The potency of an antitoxin or antiserum shall be determined by an acceptable method[7] and where applicable the unit of potency shall be the International Unit.

C.04.212. Liquid diphtheria antitoxin shall have a potency of not less than 500 International Units per millilitre.

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[1] See page 1.
[2] See page 1, A.01.010 (*s*) (*t*), C.01.006.
[3] See C.01.001 (*c*).
[4] See C.04.001 (*a*).
[5] See C.04.003.
[6] See C.04.001 (*d*).
[7] See A.01.010 (*a*).

C.04.213. Liquid tetanus antitoxin shall have a potency of not less than 400 International Units per millilitre.

C.04.214. A liquid antitoxin or antiserum shall contain not more than 20 per cent solids.

C.04.215. A dried antitoxin shall be prepared from a liquid antitoxin and, when reconstituted to the original volume of the liquid antitoxin, shall have a potency not less than that prescribed for such liquid antitoxin.

C.04.216. A dried antitoxin or antiserum shall not contain more than 1 per cent moisture as determined by an acceptable method.[1]

C.04.217. Each lot of antitoxin or antiserum shall be tested by an acceptable method[1] for pyrogenicity and it shall be pyrogen-free, and, after filling into the final containers for identity, and it shall be true to name.

C.04.218. No person shall sell an antitoxin or antiserum unless both the inner and the outer labels carry a statement of the species of animal used, when other than the horse, and the net contents in millilitres or the number of units in the container.

C.04.219. The expiration date shall be

(a) for liquid antitoxins with standards of potency

(i) not later than 12 months after the date of manufacture or the date of issue for those with a 20 per cent excess of potency,

(ii) not later than two years after the date of manufacture or the date of issue for those with a 30 per cent excess of potency,

(iii) not later than three years after the date of manufacture or the date of issue for those with a 40 per cent excess of potency, and

(iv) not later than four years after the date of manufacture or the date of issue for those with a 50 per cent excess of potency,

(b) for liquid antitoxins with no standards of potency, not later than 12 months after the date of manufacture or the date of issue,

(c) for liquid antidysentery serum, not later than 18 months after the date of manufacture or the date of issue,

(d) for any other liquid antiserum not later than 12 months after the date of manufacture or the date of issue, and

(e) for dried antitoxin and dried antiserum not later than five years after the date of manufacture or the date of issue.

Preparations from Human Sources

C.04.230. Preparations from human sources shall be pooled blood plasma, or pooled blood serum, or fractions of either separated by a method satisfactory to the Minister.

C.04.231. A manufacturer[2] shall obtain human serum, or human plasma, only from a person certified by a qualified medical practitioner to be healthy.

C.04.232. A manufacturer[2] shall not use a person to serve as a donor of blood, placenta, or cord who has a history of a disease transmissible by blood transfusion including syphilis, infectious hepatitis, or malaria.

C.04.233. The operation of drawing blood from a donor shall be under the supervision of a qualified medical practitioner, and shall be carried out in a suitable bleeding room under the control of the manufacturer.

C.04.234. A manufacturer[2] shall obtain human placenta and cord used in the manufacture of preparations from human sources only from women confined in public hospitals, and the donor of such placenta and cord shall have been free from the toxaemias of pregnancy, and the placenta and cord shall not show gross evidence of any pathological condition.

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[1] See A.01.010 (*a*).
[2] See C.04.001 (*d*).

C.04.235. Dried human serum, dried human plasma, or dried fractions of either, shall not contain more than 1 per cent moisture when determined by an acceptable method.[1]

C.04.236. A manufacturer[2] shall provide directions or means for the removal of particles of such size as to be dangerous to the recipient from preparations from human sources that are issued in fluid form or that are reconstituted from the dried form.

C.04.237. A manufacturer[2] of preparations from human sources shall maintain complete records of all donors, which records shall include the medical certificate required by C.04.231.

C.04.238. A manufacturer[2] may issue human serum, or human plasma, or fractions of either of these for prophylactic or therapeutic use in any of the following forms

(a) immune human serum, which shall be serum separated from the blood of persons recovered from the disease or from persons specifically immunized against the disease, for which the serum is intended as a prophylactic or therapeutic agent,

(b) immune human globulins, or other immune human serum fractions, which shall be prepared from immune human serum or plasma,

(c) normal human serum, or normal human plasma, or fractions of either of these prepared from the blood of normal individuals, and

(d) dried products prepared from any of these.

C.04.239. No person shall sell[3] a preparation from human sources unless both the inner and the outer labels[4] clearly indicate that the preparation is derived from human sources.

C.04.240. The expiration date[5] for preparations from human sources issued in fluid form shall be not later than 36 months after the date of filling the immediate container and for those issued in dried form, not later than five years after the date of filling the immediate container.

Antibiotics[6] for Parenteral Use[7]

C.04.300. Antibiotics for parenteral use shall meet the standards for antibiotics provided in C.01.410 to C.01.592 where applicable.

C.04.301. The provisions of C.01.004 and C.04.019 do not apply to an antibiotic[6] prepared for parenteral use,[7] but every package of such antibiotic shall carry

(a) on both the inner and the outer labels[4]

(i) the proper name[8] of the drug as specified in the licence, and where there is a proprietary or brand name the proper name shall immediately precede or follow the said proprietary or brand name in type of not less than one-half the size thereof,

(ii) the name of the manufacturer[2] or distributor,

(iii) the potency of the drug expressed in terms of International Units where established, or, if no International Unit has been established, in terms of units, milligrams or fractions of a gram, per gram in the case of solids or viscous liquids, per millilitre in the case of other liquids, or per individual dosage or dispensing form for antibiotic preparations put up in individual dosage or dispensing form,

(iv) the manufacturer's lot number,

(v) the expiration date,[5]

(vi) adequate directions for use, and

(b) on the outer label[4]

(i) the address of the manufacturer[2] or distributor,

(ii) the Canadian licence[9] number of the manufacturer[2] of the final product,

(iii) the name and amount of any preservative in the drug, and

(iv) a correct statement of the contents in terms of weight, measure, or number.

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[1] See A.01.010 (*a*).
[2] See C.04.001 (*d*).
[3] See page 1.
[4] See page 1, A.01.010 (*e*) (*i*), C.01.006.
[5] See C.01.001 (*c*).
[6] See C.01.001 (*a*).
[7] See C.01.001 (*g*).
[8] See C.01.001 (*b*).
[9] See C.04.001 (*c*).

Schedule E Drugs[1]

C.05.001. Organic compounds of arsenic and analogous preparations include

(a) **Dichlorophenarsine Hydrochloride,**

(b) **Neoarsphenamine,**

(c) **Oxophenarsine Hydrochloride,** and

(d) **Sulpharsphenamine.**

DICHLOROPHENARSINE HYDROCHLORIDE

$C_6H_6AsCl_2NO$, HCl Mol. Wt. 290·4

C.05.010. **Dichlorophenarsine Hydrochloride** shall be 3-amino-4-hydroxyphenyl-dichlorarsine hydrochloride, and, when dried in a vacuum desiccator over phosphorus pentoxide for 24 hours, shall contain not less than 25·3 per cent and not more than 27 per cent total arsenic, trivalent arsenic equivalent to not less than 97 per cent of the total arsenic, and a chlorine content determined as chloride of not less than 35·5 per cent and not more than 37 per cent, as determined by the official method,[2] and the tests for its purity are

(a) *Loss on drying*,—when dried in a vacuum desiccator over fresh *phosphorus pentoxide* for 24 hours, dichlorophenarsine hydrochloride or mixtures containing dichlorophenarsine hydrochloride lose not more than 0·5 per cent,

(b) *Solubility*,—dichlorophenarsine hydrochloride, both before and after being subjected to the thermostability test, is completely soluble in *water* as a 1 per cent solution, when tested by the official method,[2]

(c) *Thermostability*,—when tested for thermostability by the official method,[2] no marked change in colour, consistency, or solubility is found, and

(d) *Toxicity*,—the toxicity shall be equivalent to that of the Canadian Standard Dichlorophenarsine Hydrochloride as determined by the official method.[2]

C.05.011. Dichlorophenarsine hydrochloride shall be stored in a cool place, preferably not above 20°C., in hermetically sealed containers of colourless glass that have been sterilized prior to filling, and from which the air has been excluded either by the production of a vacuum or by displacement with a non-oxidizing gas.

C.05.012. Mixtures of dichlorophenarsine hydrochloride with buffering agents and substances for rendering its solution physiologically compatible with human blood shall contain total arsenic equivalent to not less than 92·5 per cent and not more than 107·5 per cent of the labelled amount of dichlorophenarsine hydrochloride; such mixtures shall meet the tests for completeness of solubility required by C.05.010 *(b)*, and shall be stored as directed in C.05.011.

C.05.013. Every manufacturer of dichlorophenarsine hydrochloride shall submit a sample of each lot of dichlorophenarsine hydrochloride manufactured by him to the Director, which sample shall consist of

(a) not less than 10 sealed ampoules of the product as completed for issue, taken by random sampling from the whole lot, and shall, in no case, consist of less than 0·6 gram of the product, and

(b) 2 ampoules of 1 gram each of pure dichlorophenarsine hydrochloride,

and each sample shall be accompanied by protocols of its tests, which protocols shall include a report of

(c) arsenic content, total and trivalent,

(d) chlorine content,

(e) moisture, and

(f) toxicity.

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[1] See page 10.
[2] See A.01.010 (*h*).

C.05.014. Upon written request from the Director a manufacturer of dichlorophenarsine hydrochloride shall submit clinical evidence of the safety of any lot of dichlorophenarsine hydrochloride manufactured by him.

C.05.015. No manufacturer shall sell[1] any dichlorophenarsine hydrochloride from a lot that has not been released by the Director.

C.05.016. Every manufacturer shall keep records in a satisfactory form respecting the manufacture, testing, and distribution of each lot of dichlorophenarsine hydrochloride manufactured by him, giving the date of such manufacture, testing or distribution, and make these records available to the Minister on request.

C.05.017. Both the inner and the outer labels[2] of dichlorophenarsine hydrochloride shall carry

(a) the quantity in grams of dichlorophenarsine hydrochloride per ampoule,

(b) the lot number,[3]

(c) the expiration date,[4] that shall be not later than three years after the date of release by the Director,

(d) the names of any admixed substances, except on the inner label of single-dose containers, and

(e) where the container is a multiple-dose container, a statement of that fact.

C.05.018. No person shall import or sell[1] any lot of dichlorophenarsine hydrochloride prepared for parenteral use[5] unless the lot conforms to the requirements of C.05.010 to C.05.017.

NEOARSPHENAMINE

$C_{12}H_{12}As_2N_2O_4SNa$ Mol. Wt. 466·1

C.05.020. **Neoarsphenamine** shall be the sodium salt of 3,3′-diamino-4,4′- dihydroxyarsenobenzene-N-methanal sulphoxylate that shall contain not less than 18 per cent and not more than 21 per cent arsenic, when determined by the official method,[6] and the tests for its purity are

(a) *Loss on drying*,—when dried for 24 hours in a vacuum desiccator over fresh *phosphorus pentoxide*, neoarsphenamine loses not more than 1·5 per cent,

(b) *Solubility*,—add 0·6 gram neoarsphenamine to 6 millilitres of *water* in a test tube and gently rotate the mixture: a complete solution results in 5 minutes,

(c) *Thermostability*,—when tested for thermostability by the official method,[6] no change in colour, consistency, or solubility is found, and

(d) *Toxicity*,—the toxicity is not greater than that of the International Reference Standard Neoarsphenamine as determined by the official method.[6]

C.05.021. Neoarsphenamine shall be stored in a cool place, preferably not above 20°C., in hermetically sealed containers of colourless glass that have been sterilized prior to filling and from which the air has been excluded either by the production of a vacuum or by displacement with a non-oxidizing gas.

C.05.022. Every manufacturer of neoarsphenamine shall submit a sample of each lot of neoarsphenamine manufactured by him to the Director, which sample shall consist of not less than 8 sealed ampoules of the product as completed for issue, taken by random sampling from the whole lot, and shall, in no case, consist of less than 7·2 grams of the product, and each sample shall be accompanied by protocols of its tests, which protocols shall include a report of

(a) arsenic content,

(b) moisture, and

(c) toxicity.

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[1] See page 1.
[2] See page 1, A.01.010 (*e*) (*i*), C.01.006.
[3] The lot number should be preceded by the words "Lot Number" or by "Lot No.", "Lot" or "(L.)"
[4] See C.01.001 (*c*).
[5] See C.01.001 (*g*).
[6] See A.01.010 (*h*).

C.05.023. Upon written request from the Director a manufacturer of neoarsphenamine shall submit clinical evidence of the safety of any lot of neoarsphenamine manufactured by him.

C.05.024. No manufacturer shall sell[1] any neoarsphenamine from a lot that has not been released by the Director.

C.05.025. Every manufacturer shall keep records in a satisfactory form respecting the manufacture, testing, and distribution of each lot of neoarsphenamine manufactured by him, giving the date of such manufacture, testing or distribution, and make these records available to the Minister on request.

C.05.026. Both the inner and the outer labels[2] of neoarsphenamine shall carry

(a) the quantity in grams of neoarsphenamine per ampoule,

(b) the lot number,[3]

(c) the expiration date,[4] that shall be not later than four years after the date of release by the Director, and

(d) where the container is a multiple-dose container, a statement of that fact.

C.05.027. No person shall import or sell[1] any lot of neoarsphenamine prepared for parenteral use[5] unless the lot conforms to the requirements of C.05.020 to C.05.026.

OXOPHENARSINE HYDROCHLORIDE

$C_6H_6AsNO_2$, HCl — Mol. Wt. 235·5

C.05.030. Oxophenarsine Hydrochloride shall be 3-amino-4-hydroxyphenylarsenoxide hydrochloride, and, when dried in a vacuum desiccator over *phosphorus pentoxide* for 24 hours, shall contain not less than 30 per cent and not more than 32 per cent total arsenic, trivalent arsenic equivalent to not less than 97 per cent of the total arsenic, and a chlorine content determined as chloride of not less than 14·8 per cent and not more than 16 per cent, when determined by the official method,[6] and the tests for its purity are

(a) *Loss on drying*,—when dried in a vacuum desiccator over fresh *phosphorus pentoxide* for 24 hours, oxophenarsine hydrochloride loses not more than 1·0 per cent; and mixtures containing oxophenarsine hydrochloride similarly tested lose not more than 0·5 per cent,

(b) *Solubility*,—oxophenarsine hydrochloride, both before and after being subjected to the thermostability test, is completely soluble in *water* as a 1 per cent solution, when tested by the official method,[6]

(c) *Thermostability*,—when tested for thermostability by the official method,[6] no marked change in colour, consistency, or solubility is found, and

(d) *Toxicity*,—the toxicity shall be equivalent to that of the Canadian Reference Standard Oxophenarsine Hydrochloride as determined by the official method.[6]

C.05.031. Oxophenarsine hydrochloride shall be stored in a cool place, preferably not above 20°C., in hermetically sealed containers of colourless glass that have been sterilized prior to filling and from which the air has been excluded either by the production of a vacuum or by displacement with a non-oxidizing gas.

C.05.032. Mixtures of oxophenarsine hydrochloride with buffering agents and substances for rendering its solution physiologically compatible with human blood shall contain total arsenic equivalent to not less than 92·5 per cent and not more than 107·5 per cent of the labelled amount of oxophenarsine hydrochloride; such mixtures shall meet the specifications for oxophenarsine hydrochloride with respect to tests for completeness of solubility required by C.05.030 *(b)*, and shall be stored as directed in C.05.031.

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[1] See page 1.
[2] See page 1, A.01.010 (*e*) (*i*), C.01.006.
[3] The lot number should be preceded by the words "Lot Number" or by "Lot No.", "Lot" or "(L.)".
[4] See C.01.001 (*c*).
[5] See C.01.001 (*g*).
[6] See A.01.010 (*h*).

C.05.033. Every manufacturer of oxophenarsine hydrochloride shall submit a sample of each lot of oxophenarsine hydrochloride manufactured by him to the Director, which sample shall consist of

(a) not less than 10 sealed ampoules of the product as completed for issue, taken by random sampling from the whole lot, and shall, in no case, consist of less than 0·6 gram of the product, and

(b) 2 ampoules of 1 gram each of pure oxophenarsine hydrochloride,

and each sample shall be accompanied by protocols of its tests, which protocols shall include a report of

(c) arsenic content, total and trivalent,

(d) moisture, and

(e) toxicity.

C.05.034. Upon written request from the Director a manufacturer of oxophenarsine hydrochloride shall submit clinical evidence of the safety of any lot of oxophenarsine hydrochloride manufactured by him.

C.05.035. No manufacturer shall sell[1] any oxophenarsine hydrochloride from a lot that has not been released by the Director.

C.05.036. Every manufacturer shall keep records in a satisfactory form respecting the manufacture, testing, and distribution of each lot of oxophenarsine hydrochloride manufactured by him, giving the date of such manufacture, testing or distribution, and make these records available to the Minister on request.

C.05.037. Both the inner and the outer labels[2] of oxophenarsine hydrochloride shall carry

(a) the quantity in grams of oxophenarsine hydrochloride per ampoule,

(b) the lot number,[3]

(c) the expiration date,[4] that shall be not later than three years after the date of release by the Director,

(d) the names of any admixed substances, except on the inner label[2] of single-dose containers, and

(e) where the container is a multiple-dose container, a statement of that fact.

C.05.038. No person shall import or sell any lot of oxophenarsine hydrochloride prepared for parenteral use[5] unless the lot conforms to the requirements of C.05.030 to C.05.037.

SULPHARSPHENAMINE

$C_{14}H_{14}As_2N_2O_8SNa_2$ Mol. Wt. 598·2

C.05.040. **Sulpharsphenamine** shall be the di-sodium salt of 3, 3′-diamino-4, 4′-dihydroxy-arsenobenzene-N-methylene sulphurous acid and shall contain not less than 18 per cent and not more than 21 per cent arsenic as determined by the official method,[6] and the tests for its purity are

(a) *Loss on drying*,—when dried for 24 hours in a vacuum desiccator over fresh *phosphorus pentoxide*, sulpharsphenamine loses not more than 2·5 per cent,

(b) *Solubility*,—add progressively 0·6 gram of sulpharsphenamine to 6 millilitres of *water* in a test tube or small cylinder and gently rotate the mixture: complete solution results in not more than 5 minutes,

(c) *Thermostability*,—when tested for thermostability by the official method,[6] no marked change in colour, consistency, or solubility is found, and

(d) *Toxicity*,—the toxicity is not greater than that of the International Reference Standard Sulpharsphenamine as determined by the official method.[6]

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[1] See page 1.
[2] See page 1, A.01 010 (*e*) (*i*), C.01.006.
[3] The lot number should be preceded by the words "Lot Number" or by "Lot No.", "Lot" or "(L.)".
[4] See C.01.001 (*c*).
[5] See C.01.001 (*g*).
[6] See A.01.010 (*h*).

C.05.041. Sulpharsphenamine shall be stored in a cool place, preferably not above 20°C., in hermetically sealed containers of colourless glass that have been sterilized prior to filling and from which the air has been excluded either by the production of a vacuum or by displacement with a non-oxidizing gas.

C.05.042. Every manufacturer of sulpharsphenamine shall submit a sample of each lot of sulpharsphenamine manufactured by him to the Director, which sample shall consist of not less than 5 sealed ampoules of the product as completed for issue, taken by random sampling from the whole lot, and shall, in no case, consist of less than 7·2 grams of the product, and each sample shall be accompanied by protocols of its tests, which protocols shall include a report of

(a) arsenic content,

(b) moisture, and

(c) toxicity.

C.05.043. Upon written request from the Director a manufacturer of sulpharsphenamine shall submit clinical evidence of the safety of any lot of sulpharsphenamine manufactured by him.

C.05.044. No manufacturer shall sell[1] any sulpharsphenamine from a lot that has not been released by the Director.

C.05.045. Every manufacturer shall keep records in a satisfactory form respecting the manufacture, testing, and distribution of each lot of sulpharsphenamine manufactured by him, giving the date of such manufacture, testing or distribution, and make these records available to the Minister on request.

C.05.046. Both the inner and the outer labels[2] of sulpharsphenamine shall carry

(a) the quantity in grams of sulpharsphenamine per ampoule,

(b) the lot number,[3]

(c) the expiration date,[4] that shall be not later than five years after the date of release by the Director, and

(d) where the container is a multiple-dose container, a statement of that fact.

C.05.047. No person shall import or sell[1] any lot of sulpharsphenamine prepared for parenteral use unless the lot conforms to the requirements of C.05.040 to C.05.046.

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[1] See page 1.
[2] See page 1, A.01.010 *(e)* (*i*), C.01.006.
[3] The lot number should be preceded by the words "Lot Number" or by "Lot No.", "Lot" or "(L.)".
[4] See C.01.001 *(c)*.

Canadian Standard Drugs

Digitalis	Injection of Digoxin
Digitoxin	Injection of Lantoside C
Digoxin	Lanatoside C
Epinephrine	Pituitary Extract (Posterior Lobe)
Epinephrine Hydrochloride Solution	Powdered Digitalis
Gelatin	Thyroid
Injection of Digitalis	Tincture of Digitalis
Injection of Digitoxin	Vitamin B_{12} with Intrinsic Factor Concentrate

General

C.06.001. In this DIVISION

(a) solubility and specific gravity shall be determined at 25°C.,

(b) reagents or solutions the names of which are printed in italics refer to reagents or solutions used in tests that are included in the ANNEX to this DIVISION or that are described in Appendix I of the British Pharmacopoeia,

(c) tests for identity, quantitative tests for arsenic, lead, copper, zinc, fluorine, and sulphur dioxide, and limit tests shall be made by acceptable methods,[1] and

(d) determination of physical and chemical constants shall be carried out by acceptable methods.[1]

DIGITALIS

C.06.100. Digitalis, Digitalis Leaf, Digitalis Leaves shall be the leaf of *Digitalis purpurea* L., rapidly dried at a temperature between 55°C. and 60°C. as soon as possible after collection, and its potency shall not be less than 10 International Units per gram, and

(*a*) its characters are

(i) *Macroscopic*,—digitalis consists of more or less crumpled or broken leaves, usually dark green on the upper surface and greyish on the under surface owing to pubescence, and with the larger veins frequently purplish; as a rule they vary from 10 to 30 centimetres in length and from 4 to 10 centimetres in width; in shape, they vary from ovate-lanceolate to broadly ovate, and petiolate; they have an irregularly crenate or serrate margin, decurrent at the base and sub-acute at the apex; the upper surface is hairy, the under surface densely pubescent and the veinlets reticulate,

(ii) *Microscopic*,— the upper epidermis has slightly wavy vertical walls, with few or no stomata; the under epidermis is similar, but with numerous stomata and many hairs; over irregular areas, especially near the veins, the hairs are frequently not attached to the cell structure within; the hairs are simple, usually 3 to 5 cells in length, bluntly pointed and finely wavy; the glandular hairs consist usually of a unicelular pedicel bearing a one-celled or two-celled head; the chlorenchyma consists of a single layer of palisade cells and several layers of spongy parenchyma; there are numerous fibro-vascular bundles in the larger veins and in the petiole, separated by medullary rays one cell wide; the tracheae are annular, reticulate, or spiral; calcium oxalate and sclerenchymatous elements are absent, and

(iii) digitalis has a slight odour when dry, but peculiar and characteristic when moistened; and a decidedly bitter taste, and

(*b*) the tests for its purity are

(i) *Loss on drying*,—when dried at 100°C., digitalis loses not more than 6 per cent,

(ii) *Acid-insoluble ash*,—the acid-insoluble ash of digitalis does not exceed 5 per cent, and

(iii) *Foreign organic matter*,—digitalis does not contain more than 2 per cent foreign organic matter, including stems, browned leaves, or flowers.

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[1] See A.01.010 (*a*).

C.06.101. Digitalis shall be

(a) assayed by the official method,[1] and

(b) stored to prevent access of moisture in a tightly-closed container that includes where necessary a device containing a non-liquefying, inert, dehydrating substance to control the humidity.

Preparations: Powdered Digitalis
Tincture of Digitalis

NOTE: When Digitalis, Digitalis Folia, Digitalis Folium, or Pulvis Digitalis is prescribed, Powdered Digitalis shall be dispensed.

DIGITOXIN

C.06.120. **Digitoxin** shall be either pure digitoxin ($C_{41}H_{64}O_{13}$) or a mixture of cardioactive glycosides that consist chiefly of digitoxin obtained from *Digitalis purpurea* L., and shall correspond in potency to the Canadian Standard Digitoxin, and

(a) its characters are

(i) *Description,*— digitoxin is a white or pale buff, odourless, microcrystalline powder, and

(ii) *Solubility,*—digitoxin is insoluble in *water* and very slightly soluble in *ether*, and 1 gram dissolves in

(1) approximately 10 millilitres of *chloroform*, and

(2) approximately 60 millilitres of *alcohol (95 per cent)*,

(b) the test for its identity is: add 0·5 millilitre of *test-solution of ferric chloride* to 100 millilitres of *glacial acetic acid*, and mix well; dissolve about 1 milligram of digitoxin in 2 millilitres of this solution and underlay it with 2 millilitres of *sulphuric acid:* a brown colour is produced at the zone of contact of the two liquids which gradually changes to light green, then to blue, and finally the entire acetic acid layer acquires a blue colour, and

(c) the tests for its purity are

(i) *Completeness of solution in chloroform,*—frequently agitate 100 milligrams of digitoxin with 5 millilitres of *chloroform* in a tightly stoppered cylinder: the digitoxin dissolves completely within 24 hours with or without opalescence,

(ii) *Digitonin,*—dissolve 10 milligrams of digitoxin in 2 millilitres of *alcohol (95 per cent)* in a test tube the inner wall of which is free from scratches, add 2 millilitres of *solution of cholesterol*, and mix by gentle agitation: no precipitate is formed within 10 minutes,

(iii) *Loss on drying,*—when dried at 100°C. for 2 hours digitoxin loses not more than 1 per cent, and

(iv) *Ash,*—when incinerated, digitoxin leaves not more than 0·05 per cent ash.

C.06.121. Digitoxin shall be

(a) assayed by the official method,[1] and

(b) stored in tightly closed containers.

C.06.122. Both the inner and the outer labels[2] of digitoxin shall carry

(a) the number of milligrams of digitoxin and an equivalent statement of the strength in terms of the digitalis leaf per tablet or other individual dosage or dispensing form, and

(b) the lot number.[3]

USUAL DOSE

Metric	*Imperial*
0·1 to 0·2 milligram	1/600 to 1/300 grain

[1] See A.01.010 (*h*).
[2] See page 1, A.01.010 (*e*) (*i*), C.01.006.
[3] The lot number should be preceded by the words "Lot Number", or by "Lot No.", "Lot"or "(L.)".

DIGOXIN

$C_{41}H_{64}O_{14}$ Mol. Wt. 780·9

C.06.130. Digoxin shall be a glycoside obtained from the leaves of *Digitalis lanata* Ehrh., and shall correspond in potency to Canadian Standard Digoxin, and

(a) its characters are

(i) *Description,*—digoxin occurs as colourless to white crystals or as a white crystalline powder that is odourless, and melts indistinctly, and with decomposition, at approximately 265°C.,

(ii) *Solubility,*—digoxin is insoluble in

(1) *water.*

(2) *chloroform,*

(3) *ether,* but

freely soluble in *pyridine,* and soluble in *alcohol (50 per cent),* and

(iii) *Specific rotation,*—the *specific rotation,* $[\alpha]_D^{25}$, of digoxin, determined in a solution in *anhydrous pyridine* containing 1 gram of digoxin in 10 millilitres of solution, using a mercury light at 546 mμ and a 200-millimetre tube, is between 13·4° and 13·8°,

(b) the test for its identity is: add 0·5 millilitre of *test-solution of ferric chloride* to 100 millilitres of *glacial acetic acid* and mix well; dissolve about 1 milligram of digoxin in 2 millilitres of this solution and underlay with 1 millilitre of *sulphuric acid:* a brown ring, free from red, is produced at the junction of the two liquids; after some time the acetic acid layer acquires a blue colour, and

(c) the tests for its purity are

(i) *Loss on drying,*—when dried at 60°C. in a vacuum over *sulphuric acid,* digoxin loses not more than 0·5 per cent, and

(ii) *Ash,*—when incinerated, digoxin leaves not more than 0·05 per cent ash.

C.06.131. Digoxin shall be

(a) assayed by the official method,[1] and

(b) stored in tightly-closed containers, protected from light.

C.06.132. Both the inner and the outer labels[2] of digoxin shall carry

(a) the number of milligrams of digoxin per tablet or other individual dosage or dispensing form, and

(b) the lot number.[3]

USUAL DOSE

Metric	*Imperial*
0·25 milligram	1/260 grain

EPINEPHRINE

$C_9H_{13}NO_3$ Mol. Wt. 183·2

C.06.140. Epinephrine shall be (—) —1-3:'4' dihydroxyphenyl-2-methyl-aminoethanol, and

(a) its characters are:

(i) *Description,*—epinephrine occurs as a white or light brownish microcrystalline, odourless powder, gradually darkening on exposure to air or light and its solutions are slightly alkaline to *litmus* and turn brown on exposure to light,

(ii) *Solubility,*—epinephrine is

(1) very slightly soluble in

(a) water, and

(b) alcohol (95 per cent), and

(2) insoluble in

(a) ether,

(b) chloroform, and

(c) fixed and volatile oils, and

[1] See A.01.010 (*h*).
[2] See page 1, A.01.010 (*e*) (*i*), C.01.006.
[3] The lot number should be preceded by the words "Lot Number" or by "Lot No.", "Lot" or "(L.)"

(iii) *Specific rotation,*—the specific rotation, α_D^{25}, of epinephrine is between −50° and 53·5° and is determined using a solution obtained by dissolving 1 gram of epinephrine, previously dried over *sulphuric acid* to constant weight, in sufficient *N/2 hydrochloric acid* to make 20 millilitres at 25°C., and using a 200-millimetre tube,

(b) the tests for its identity are

(i) dilute 2 millilitres of a slightly acid solution of epinephrine (1:1,000) to 10 millilitres with *water*. Add 1 drop of a 0·25 per cent w/v solution of *ferric chloride* in *water:* an emerald green colour develops, and, on the gradual addition of *solution of sodium bicarbonate*, this colour changes first to blue and then to red, and

(ii) other oxidizing agents produce red, pink, or violet colours which change to brown, and

(c) the tests for its purity are

(i) *Plant alkaloids,*—an acid solution of epinephrine (1:1,000) is not visibly affected by solutions of *trinitrophenol, tannic acid, phosphomolybdic acid, platinic chloride,* or *solution of potassium mercuri-iodide:*

(ii) *Loss on drying*—when dried in a vacuum over *sulphuric acid* for 18 hours, epinephrine loses not more than 2 per cent,

(iii) *Ash*—when incinerated, epinephrine leaves not more than 0·05 per cent ash, and

(iv) *Limit of arterenal*—4 per cent, as determined by an acceptable method.[1]

C.06.141. Epinephrine shall be stored in tightly closed containers, protected from light.

C.06.142. Both the inner and the outer labels[2] of epinephrine shall carry the lot number.[3]

EPINEPHRINE HYDROCHLORIDE SOLUTION

C.06.150. **Epinephrine Hydrochloride Solution** shall be a solution of epinephrine in distilled water acidulated with hydrochloric acid and its stated concentration shall correspond in bronchodilator and pressor potencies to that of a solution of Canadian Standard Epinephrine of the same stated concentration, and

(a) its characters are: *Description,*—epinephrine hydrochloride solution is a nearly colourless, slightly acid liquid, gradually turning dark on exposure to air or light, but if the solution is brown in colour, or contains a precipitate, it shall not be used, and

(b) the test for its identity is: dilute 2 millilitres of epinephrine hydrochloride solution (1:1,000) to 10 millilitres with *water*. Add 1 drop of a 0·25 per cent w/v solution of *ferric chloride* in *water:* an emerald green colour develops, and, on the gradual addition of *solution of sodium bicarbonate*, this colour changes first to blue and then to red, and

(c) *Acidity,*—a 0·1 per cent solution of epinephrine hydrochloride shall have a pH of not less than 2·5 and not more than 5.

C.06.151. Epinephrine hydrochloride solution shall be

(a) assayed by an acceptable method[1], and

(b) stored in a cool place in well-filled, tightly-closed containers, protected from light.

C.06.152. Both the inner and the outer labels[2] of epinephrine hydrochloride solution shall carry

(a) the concentration (for example, 1:100 or 1:1,000),

(b) the lot number[3], and

(c) the expiration date[4], except on the inner label of single-dose containers.

C.06.153. The expiration date[4] for epinephrine hydrochloride solution shall be not later than 18 months after assay.

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[1] See A.01.010 (*a*).
[2] See page 1, A.01.010 (*e*) (*i*), C.01.006.
[3] The lot number should be preceded by the words "Lot Number" or by "Lot No." "Lot" or "(L.)"
[4] See C.01.001 (*c*).

EPINEPRHINE BITARTRATE

$C_9H_{13}O_3N,C_4H_6O_6$ Mol. Wt. 333·3

C.06.154. Epinephrine Bitartrate shall be the acid tartrate of (—) −1-3':4'-dihydroxyphenyl-2-methylaminoethanol, and

(a) its characters are

(i) *Description,*—epinephrine bitartrate occurs as a white greyish-white, or light brownish-grey, crystalline powder. It is odourless and slowly darkens on exposure to air and light, and

(ii) *Solubility,*—epinephrine bitartrate is

(1) soluble in

(a) water, and slightly soluble in

(b) alcohol (95 per cent), and

(2) insoluble in

(a) chloroform, and

(b) ether,

(b) the tests for its identity are

(i) dissolve 0·3 g. in 10 ml. of *water* containing 0·1 g. of *sodium metabisulphite,* add a slight excess of *dilute solution of ammonia,* and allow to stand at about 4°C. for one hour. Filter, wash the precipitate with 3 successive quantities, each of 2 ml. of cold *water,* then with 5 ml. of cold *alcohol (95 per cent)* and finally with 5 ml. of cold *ether,* and dry over *phosphorous pentoxide* at a pressure not exceeding 5 mm. of *mercury* for three hours. The residue complies with the test for specific rotation and identity as described in C.06.140 *(a)* (iii) and *(b),* and

(ii) the filtrate obtained in the test for identity yields the reactions characteristic of tartrates, as described in C.06.157, and

(c) the tests for its purity are

(i) *Loss on drying,*—when dried in a vacuum over *sulphuric acid* for 3 hours, epinephrine bitartrate loses not more than 0·5 per cent,

(ii) *Ash,*—when incinerated, ephinephrine bitartrate leaves not more than 0·1 per cent ash,

(iii) *Melting range,*—epinephrine bitartrate melts between 147°C and 152°C.,

(iv) *Nitrogen content,*—the nitrogen content shall be not less than 4·1 per cent and not more than 4·3 per cent as determined by an acceptable method[1], and

(v) *Limit of arterenal,*—4 per cent, as determined by an acceptable method[1].

C.06.155. Epinephrine bitartrate shall be stored in tightly-closed containers, protected from light.

C.06.156. Both the inner and the outer labels[2] of epinephrine bitartrate shall carry the lot number[3].

EPINEPHRINE BITARTRATE SOLUTION

C.06.157. Epinephrine Bitartrate Solution shall be a solution of epinephrine acid tartrate in distilled water and its stated concentration shall correspond in bronchodilator and pressor potencies to that of a solution of Canadian Standard Epinephrine of the same stated concentration, and

(a) its characters are: *Description,*—epinephrine bitartrate solution is a nearly colourless slightly acid liquid, gradually turning dark on exposure to air or light, but if the solution is brown in colour, or contains a precipitate, it shall not be used, and

(b) the test for its identify is

(i) For epinephrine,—dilute 2 millilitres of a 1:1,000 solution to 10 millilitres with *water.* Add 1 drop of a 0·25 per cent w/v solution of *ferric chloride* in *water:* an emerald green colour develops, and, on the gradual addition of a *solution of sodium bicarbonate,* this colour changes first to blue and then to red.

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[1] See A.01.010 *(a).*
[2] See page 1, A.01.010 *(e)* *(i),* C.01.066.
[3] The Lot number should be preceded by the words "Lot Number" or by "Lot No.", "Lot" or "L.)".

(ii) For tartrate,—to 10 millilitres of a 1:1,000 solution and 0·1 gram of *sodium metabisulphite*, then add *dilute solution of ammonia* until the solution has a distinct odour of ammonia, and allow to stand at about 4°C. for one hour. Filter and test filtrate for tartrates viz: make filtrate acid to *blue litmus paper* with *acetic acid*, add 1 drop of *solution of ferrous sulphate*, 2 drops of *solution of hydrogen peroxide* and slowly add an excess of *solution of sodium hydroxide*. A purple colour is produced.

(c) *Acidity*—a 0·1 per cent w/v solution in *water* of epinephrine bitartrate shall have a pH of not less than 2·8 and not more than 3·8.

C.06.158. Epinephrine Bitartrate Solution shall be

(a) assayed by an acceptable method[1], and

(b) stored in a cool place in well-filled, tightly-closed containers, protected from light.

C.06.159. Both the inner and outer labels[2] of epinephrine bitartrate solution shall carry

(a) the concentration (for example, 1:100 or 1:1,000),

(b) the lot number[3], and

(c) the expiration date[4], except on the inner label of single-dose containers.

C.06.160. The expiration date[4] for epinephrine bitartrate solution shall be not later than 18 months after assay.

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[1] See A.01.010 (*a*).
[2] See page 1, A.01.010 (*e*) (*i*), C.01.006.
[3] The Lot number should be preceded by the words "Lot Number" or by "Lot No.", "Lot" or "(L)".
[4] See C.01.001 (*c*).

GELATIN

C.06.170. **Gelatin** shall be the protein that is obtained by extraction of collagenous material, and

(a) its characters are

(i) *Description*,—gelatin occurs in translucent sheets, shreds, powder, or granules that are colourless or pale-yellowish in colour and possess a slight odour and taste, and

(ii) *Solubility*,—gelatin is

(1) insoluble in

(a) cold *water*, but swells and softens when immersed in it,

(b) *alcohol (90 per cent)*,

(c) *solvent ether*, and

(d) *chloroform*, and

(2) soluble in

(a) hot *water*, forming a jelly on cooling,

(b) a cold mixture of *glycerin* and *water*, and

(c) *acetic acid*,

(b) the tests for its identity are

(i) a dilute solution of gelatin in *water* produces a precipitate with

(1) *solution of trinitrophenol*,

(2) *solution of tannic acid*,

(3) solutions of *chromium trioxide*,

but not with

(4) other acids,

(5) a dilute solution of *alum*,

(6) *solution of lead acetate*, or

(7) *test-solution of ferric chloride*,

(ii) when heated with *soda lime*, it evolves ammonia, and

(iii) a solution in *water* produces, with *solution of mercury nitrate*, a white precipitate which develops a brick-red colour on warming, and

(c) the tests for its purity are

(i) *Arsenic*,—the *arsenic limit* shall be 2 parts per million,

(ii) *Copper*,—the *copper limit* shall be 30 parts per million,

(iii) *Fluorine*,—the *fluorine limit* shall be 2 parts per million,

(iv) *Lead*,—the *lead limit* shall be 7 parts per million,

(v) *Sulphur dioxide*,—the *sulphur dioxide limit* shall be 500 parts per million,

(vi) *Zinc*,—the *zinc limit* shall be 100 parts per million,

(vii) *Odour and taste of a solution*,—a warm 5 per cent w/v solution of gelatin in *water* shall be free from objectionable taste and offensive odour,

(viii) *Loss on drying*,—gelatin shall lose not more than 16 per cent when dried,

(ix) *Ash*,—gelatin shall leave not more than 2·6 per cent ash, as determined by the official method,[1] and

(x) *Bacterial content*,—gelatin shall not show the presence of more than 10,000 bacteria per gram and coliform bacteria shall not be evident in 0·01 gram, as determined by the official method.[1]

INJECTION OF DIGITALIS

C.06.180. **Injection of Digitalis** shall be a solution of one or more of the glycosides or of the therapeutically desirable and cardioactive constituents of *Digitalis purpurea* L., in sterilized water or in diluted alcohol and shall be assayed by the official method.[1]

C.06.181. Both the inner and the outer labels[2] of injection of digitalis shall carry

(a) the potency in International Units per millilitre,

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[1] See A.01.010 (*h*).
[2] See page 1, A.01.010 (*e*) (*i*), C.01.006.

119, June 7, 1956.
Replaces page 119, August 10, 1955.

(b) the lot number,[1] and

(c) the expiration date,[2] except on the inner label of containers containing 2 millilitres or less.

C.06.182. The outer label[3] of injection of digitalis shall carry the following statement or words of like import:

Caution: one digitalis unit given intravenously generally has a greater effect than the same amount given orally. Physicians are advised to take cognizance of the fact when administering injection of digitalis.

C.06.183. The expiration date[2] for injection of digitalis shall be not later than two years after the date of assay.

INJECTION OF DIGITOXIN

C.06.190. **Injection of Digitoxin** shall be a solution of digitoxin in alcohol (40 to 50 per cent v/v) and may also contain glycerin, and shall be

(a) assayed by the official method,[4] and

(b) stored in single-dose hermetically sealed containers protected from light.

C.06.191. Both the inner and the outer labels[3] of injection of digitoxin shall carry

(a) the amount of digitoxin contained in each millilitre, and

(b) the lot number[1].

INJECTION OF DIGOXIN

C.06.200. **Injection of Digoxin** shall be a solution of digoxin in alcohol (10 per cent v/v) and may contain other solubilizing agents, and shall be

(a) assayed by the official method,[4] and

(b) stored in single-dose hermetically sealed containers protected from light.

C.06.201. Both the inner and the outer labels[3] of injection of digoxin shall carry

(a) the amount of digoxin contained in each millilitre, and

(b) the lot number.[1]

INJECTION OF LANATOSIDE C

C.06.210. **Injection of Lanatoside C** shall be a solution of lanatoside C in alcohol (10 per cent v/v) and may also contain glycerin, and shall contain, in each millilitre, the labelled amount of lanatoside C, and shall be

(a) assayed by the official method,[4] and

(b) stored in single-dose hermetically sealed containers protected from light.

C.06.211. Both the inner and the outer labels[3] of injection of lanatoside C shall carry

(a) the amount of lanatoside C contained in each millilitre, and

(b) the lot number.[1]

USUAL DOSE

See under Lanatoside C

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[1] The lot number should be preceded by the words "Lot Number" or by "Lot No.", "Lot" or "(L.)".
[2] See C.01.001 (*c*).
[3] See page 1, A.01.010 (*e*) (*i*), C.01.006.
[4] See A.01.010 (*h*).

LANATOSIDE C

$C_{49}H_{76}O_{20}$ Mol. Wt. 984·6

C.06.220. Lanatoside C shall be a glycoside obtained from the leaves of *Digitalis lanata* Ehrh., and

(a) its characters are

(i) *Description,*—lanatoside C occurs as colourless or white crystals or as a white crystalline powder that is

(1) odourless,

(2) melts indistinctly and with decomposition at approximately 250°C., and

(3) is hygroscopic, rapidly absorbing approximately 7 per cent moisture when exposed to air,

(ii) *Solubility,*—lanatoside C is

(1) insoluble in *water*,

(2) practically insoluble in *ether*,

(3) practically insoluble in *light petroleum*,

(4) sparingly soluble in *alcohol (95 per cent)*,

(5) soluble in *dioxan*,

(6) soluble in *pyridine*,

(7) soluble, 1:20 w/v, in *methyl alcohol*, and

(8) soluble, 1:2,000 w/v, in *chloroform*, and

(iii) *Specific rotation,*—the *specific rotation*, $[\alpha]_D^{25}$, of lanatoside C is between 33·4° and 33·7° and is determined using a solution in *alcohol (95 per cent)* containing the equivalent of 200 milligrams of dried lanatoside C in 10 millilitres of the solution, and using a 100-millimetre tube,

(b) the test for its identity is: add 0·5 millilitre of *test-solution of ferric chloride* to 100 millilitres of *glacial acetic acid*, and mix well: dissolve 2 to 3 milligrams of lanatoside C in 5 millilitres of this solution, and underlay with 5 millilitres of *sulphuric acid:* an intense indigo-blue colour is immediately formed in the acetic acid layer, and a brown ring, free from red, is produced at the junction of the two liquids, and

(c) the tests for its purity are

(i) *Loss on drying,*—when dried in a vacuum over *sulphuric acid* to constant weight, lanatoside C loses not more than 7·5 per cent, and

(ii) *Ash,*—when incinerated, lanatoside C leaves not more than 0·05 per cent ash.

C.06.221. Lanatoside C shall be

(a) assayed by the official method,[1] and

(b) stored in closed containers protected from light.

C.06.222. Both the inner and the outer labels[2] of lanatoside C shall carry

(a) the number of milligrams of lanatoside C per tablet or other individual dosage or dispensing form, and

(b) the lot number.[3]

USUAL DOSE

Metric	*Imperial*
0·25 to 0·75 milligram	1/260 to 1/80 grain

PITUITARY EXTRACT (POSTERIOR LOBE)

C.06.230. Pituitary Extract (Posterior Lobe) shall be the aqueous extract prepared from the separated posterior lobe of the pituitary bodies of oxen or other mammals, and

(a) its character is: *Description,*—pituitary extract (posterior lobe) is a clear, colourless liquid with a faint odour, and shall have a pH of not less than 3 and not more than 4, and

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[1] See A.01.010 (*h.*)

[2] See page 1, A.01.010 (*e*) (*i*), C.01.006.

[3] The lot number should be preceded by the words "Lot Number" or by "Lot No.", "Lot" or "(L.)".

(*b*) the tests for its identity are

(i) pituitary extract (posterior lobe) causes contraction of the uterine muscle of the guinea-pig suspended in a suitable bath,

(ii) pituitary extract (posterior lobe) causes a rise of the blood pressure when injected into the vein of a mammal anaesthetized by a general anaesthetic or by destruction of the brain,

(iii) when injected under the skin of a mammal, at the same time as a volume of water is administered by mouth, pituitary extract (posterior lobe) causes a delay in the excretion of the water, and

(iv) when mixed with an equal volume of 2*N sodium hydroxide* and allowed to stand for 1 hour at room temperature, and then neutralized, the actions on the blood pressure and excretion of water disappear, and the activity on the uterine muscle of the guinea-pig is reduced to not more than 5 per cent of that originally present.

C.06.231. Pituitary extract (posterior lobe) shall be

(*a*) assayed by the official method,[1] and

(*b*) stored in single-dose hermetically sealed containers that should be maintained at as low a temperature as possible above its freezing point, and the glass ampoules, or glass vials shall meet the tests for *limit of alkalinity of glass*.

C.06.232. Both the inner and the outer labels[2] of pituitary extract (posterior lobe) shall carry

(*a*) the potency in International Units per millilitre, except in the case of single-dose containers of 1 millilitre or less, where the potency shall be expressed in International Units,

(*b*) the lot number,[3] and

(*c*) the expiration date[4], except on the inner label[2] of single-dose containers.

C.06.233. The expiration date for pituitary extract (posterior lobe) shall be not later than eighteen months after the date of assay.

USUAL DOSE

Metric	*Imperial*
0·2 to 0·5 millilitre	3 to 8 minims

(representing between 2 and 5 International Units)

POWDERED DIGITALIS

C.06.240. **Powdered Digitalis** shall be digitalis dried at a temperature not exceeding 60°C. and reduced to a fine powder, of which all will pass through a 177-micron sieve and not more than 40 per cent through a 125-micron sieve (Canadian Standard Specification, 8-GP-1), and for therapeutic administration, shall be assayed and adjusted to contain 10 International Units in 1 gram, for which purpose, powdered digitalis, containing more than 10 International Units in 1 gram, may be adjusted to contain 10 International Units in 1 gram, by thorough mixture with powdered digitalis containing less than 10 International Units in 1 gram, or with the exhausted marc remaining when tincture of digitalis has been prepared, the marc being carefully dried before mixing, and the test for its purity is: *Loss on drying*,—when dried at 100°C., powdered digitalis loses not more than 5 per cent.

C.06.241. Powdered digitalis shall be

(*a*) assayed by the official method,[1] and

(*b*) stored to prevent access of moisture in a tighly-closed container that includes where necessary a device containing a non-liquefying, inert, dehydrating substance to control the humidity.

C.06.242. Both the inner and the outer labels[2] of powdered digitalis shall carry

(*a*) the potency in International Units per gram, or per tablet or other individual dosage or dispensing form,

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[1] See A.01.010 (*h*).
[2] See page 1, A.01.010 (*e*) (*i*), C.01.006.
[3] The lot number should be preceded by the words "Lot Number" or by "Lot No.", "Lot" or "(L)"
[4] See C.01.001 (*c*)

(b) a statement of the number of grains of powdered digitalis per tablet or other individual dosage or dispensing form, and

(c) the lot number.[1]

USUAL DOSE

(Maintenance)

Metric	*Imperial*
30 to 100 milligrams	½ to 1½ grains

THYROID

C.06.250. **Thyroid** shall be the cleaned, dried, powdered thyroid glands of domestic animals used for food, and shall contain not less than 0·17 per cent, and not more than 0·23 per cent iodine and no added iodine in either inorganic or organic form, and

(a) its characters are

Description,—

(i) *General,*—thyroid occurs as a cream-coloured, amorphous powder; the odour and taste are faint and meat-like, and

(ii) *Microscopical,*—when suitably mounted and examined under the microscope, thyroid shows the following: numerous smooth to striated hyaline fragments of colloids, of angular to irregular shape, that are colourless to pale yellow in water mounts, brown in *Mallory's stain* and pink in *solution of eosin*, some of these fragments containing granules, minute vacuoles, crystalloidal bodies and cells; numerous irregular fragments of follicular epithelium staining brown with *Mallory's stain*, the individual cells more or less polygonal to rounded-angular or irregularly cuboidal, often with prominent nuclei staining dark blue, their cytoplasm purplish with *Delafield's solution of haematoxylin;* slender glistening segments of capillaries of closely undulate outline; numerous slender segments of neuraxons; numerous aggregates of particles of intercellular substance and slender, mostly straight connective tissue fibres staining blue to greenish blue with a mixture of *Mallory's stain* and *solution of phosphotungstic acid*, the bundles of fibres often appearing reddish in *Mallory's stain;* few glistening fragments of blood vessels with serrated or crenated ends as viewed in water mounts, and

(b) the tests for its purity are

(i) *Inorganic iodine,*—add to 1 gram of thyroid 10 millilitres of a saturated solution of *zinc sulphate* in *water*, shake, allow to stand 5 minutes, and filter through a fritted glass filter; add to 5 millilitres of the filtrate 0·5 millilitre of *mucilage of starch* and 4 drops each of a 10 per cent w/v solution of *sodium nitrite* in *water* and *dilute sulphuric acid*, shaking after each addition: no blue colour is produced, and

(ii) *Moisture,*—thyroid loses not more than 6 per cent moisture.

C.06.251. Thyroid shall be

(a) assayed by the official method,[2] and

(b) stored in a cool place and in a tightly-closed container.

C.06.252. Both the inner and the outer labels[3] of thyroid shall carry the lot number.[1]

USUAL DOSE

(Maintenance)

Metric	*Imperial*
30 to 120 milligrams	½ to 2 grains

[1] The lot number should be preceded by the words "Lot Number" or by "Lot No.", "Lot" or "(L.)".
[2] See A.01.010 (*h.*)
[3] See page 1, A.01.010 (*e*) (*i*), C.01.006.

TINCTURE OF DIGITALIS

C.06.260. **Tincture of Digitalis** shall have a potency of one International Unit per millilitre and shall be prepared in accordance with a direct ratio to a 1 litre lot thereof that shall be prepared from

(a) Digitalis, in No. 40 powder.....100 grams

(b) Alcohol (70 per cent).....a sufficient quantity,

by the Percolation Process of the British Pharmacopoeia and collecting 900 millilitres that after assay is adjusted with a sufficient quantity of alcohol (70 per cent) to produce a tincture of digitalis of a potency of one International Unit per millilitre.

C.06.261. Tincture of digitalis shall be assayed by the official method.[1]

C.06.262. The *alcohol content* of tincture of digitalis shall be between 65 per cent and 70 per cent v/v alcohol (C_2H_5OH).

C.06.263. Both the inner and the outer labels[2] of tincture of digitalis shall carry

(a) the potency in International Units per millilitre,

(b) the lot number,[3] and

(c) the expiration date.[4]

C.06.264. The expiration date[4] for tincture of digitalis shall be not later than two years after the date of assay.

Usual Dose (Maintenance)	
Metric	*Imperial*
0·3 to 1 millilitre	5 to 15 minims

VITAMIN B_{12} WITH INTRINSIC FACTOR CONCENTRATE

C.06.270. **Vitamin B_{12} with Intrinsic Factor Concentrate** shall be the preparation possessing vitamin B_{12} activity made more assimilable from the gastro-intestinal tract by combination with suitable preparations of the mucosa of the stomach or intestines of animals used for food by man, which preparation when administered orally to persons affected with pernicious anaemia shall produce a remission of the disorder.

C.06.271. The approximate anti-anaemia potency of vitamin B_{12} with intrinsic factor concentrate shall be determined by clinical tests and shall be expressed only in Oral Units, and no reference shall be made to the content of vitamin B_{12}.

C.06.272. An Oral Unit shall be the activity of that amount of an otherwise acceptable product that produces, when administered by mouth daily, satisfactory clinical and hematopoietic responses in Addisonian pernicious anaemia and shall contain vitamin B_{12} activity equivalent to not more than 15 micrograms of cyanocobalamin and not more than 300 milligrams on the dry basis of the preparation constituting the intrinsic factor concentrate.

C.06.273. No person shall sell[5] vitamin B_{12} with intrinsic factor concentrate unless the manufacturer has submitted to the Director

(a) a description of the methods and controls used for the manufacturing, processing, and packaging of the drug,

(b) protocols of tests performed by an acceptable method[6] on at least 2 different lots of the drug with at least 3 patients to indicate that the drug is effective in producing satisfactory clinical and hematopoietic responses in Addisonian pernicious anaemia when manufactured by the described method and when administered as recommended in the statement of dosage.

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[1] See A.01.010 (*h*).
[2] See page 1, A.01.010 (*e*) (*i*), C.01.006.
[3] The lot number should be preceded by the words "Lot Number" or by "Lot No.", "Lot" or "(L.)".
[4] See C.01.001. (*c*).
[5] See page 1.
[6] See A.01.010 (*a*).

C.06.274. No person shall sell[1] vitamin B_{12} with intrinsic factor concentrate unless the information required by C.06.273 is supplied

(a) prior to sale,

(b) every two years from current lots, and

(c) when alterations are made in the method of manufacture.

C.06.275. Both the inner and the outer labels[2] of a drug represented as containing vitamin B_{12} with intrinsic factor concentrate shall carry a statement

(a) of the anti-anaemia potency expressed in Oral Units,

(b) of the recommended daily dose, which shall contain at least one Oral Unit of anti-pernicious anaemia activity,

(c) "NOTE: For Therapeutic Use Only", and

(d) that the container should be kept tightly closed and in a cool place.

C.06.276. Drugs represented as containing vitamin B_{12} with intrinsic factor concentrate shall not be advertised to the general public.

C.06.277. No person shall mention on a label[2] or in an advertisement intrinsic factor or intrinsic factor concentrate unless it conforms to all the requirements of vitamin B_{12} with intrinsic factor concentrate.

C.06.278. Vitamin B_{12} with Intrinsic Factor Concentrate and other medication shall meet all the requirements of vitamin B_{12} with intrinsic factor concentrate in respect to that ingredient and shall carry on both the inner and the outer labels[2] a statement

(a) of the true nature and amount of the added medication, that notwithstanding C.06.271 may include vitamin B_{12}, with observance of any requirement of these regulations in respect of such added medication, and the words *other medication* may be replaced by the proper name of such added medication, and

(b) that the potency of vitamin B_{12} with intrinsic factor concentrate was established prior to mixture with such added medication.

C.06.279. No person shall sell[1] a drug for oral use for the treatment of pernicious anaemia unless

(a) the drug meets all the requirements of C.06.273 to C.06.276, and

(b) the anti-anaemia potency is expressed in Oral Units which have the activity described in C.06.272.

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[1] See page 1.
[2] See page 1, A.01.010 (*e*) (*i*), C.01.006.

Reagents or Solutions Employed in Tests

Aniline Blue is the water-soluble dye that consists of a mixture of the trisulphonates of triphenyl-*p*-rosaniline and diphenyl-*p*-rosaniline.

Cholesterol is cholesterol of pharmacopoeial grade.

Solution of Cholesterol is a 0·5 per cent w/v solution of cholesterol in *alcohol (95 per cent)*.

Delafield's Solution of Haematoxylin is made by dissolving 4 grams of haematoxylin in 25 millilitres of *alcohol (95 per cent)*, mixing with 400 millilitres of a saturated solution of *ammonium alum* in *water*, and setting aside for 4 days in a flask closed with a plug of cotton wool, exposed to light and air; this solution is then mixed with 200 millilitres of a mixture of equal volumes of *glycerin* and *methyl alcohol*, allowed to stand for 6 weeks in a warm place exposed to light until the colour darkens, and is kept in a tightly-stoppered bottle.

Mallory's Stain is made by dissolving 0·5 gram of *aniline blue*, 2 grams of *orange G*, and 2 grams *oxalic acid* in 100 millilitres of *water*.

Orange G is the di-sodium salt of 1-phenylazo-2-naphthol-6, 8-disulphonic acid.

Phosphotungstic Acid is phosphotungstic acid of reagent purity.

Solution of Phosphotungstic Acid is a 1 per cent w/v solution of phosphotungstic acid in *water*.

Solution of Sodium Hypochlorite is a freshly prepared solution made by dissolving 10·5 grams of *sodium carbonate* in 25 millilitres of *water*, mixing with the liquid obtained by thoroughly triturating 7 grams of *chlorinated lime* with 75 millilitres of *water*, shaking frequently during 3 or 4 hours, and filtering.

Part D

VITAMINS

Division 1

General

D.01.001. In this **Part**

(a) "common name" means, with reference to a food, the name of the food printed in bold-face type in these regulations or, if the name of the food is not so printed, the name in English or French by which the food is generally known,

(b) "food colour" means those colours permitted for use in or upon food by **Part B**, Division 6 of these regulations,

(c) "official drug" means any drug

(i) for which a standard is provided in these regulations or

(ii) for which no standard is provided in these regulations but for which a standard is provided in any of the publications mentioned in SCHEDULE B[1] to the Act,

(d) "parenteral use" means administration of a drug by means of hypodermic syringe, needle or other instrument through or into the skin or mucous membrane,

(e) "per cent" means per cent by weight unless otherwise stated,

(f) "practitioner" means a person authorized by the law of a province of Canada to treat patients with any drug listed or described in SCHEDULE F[2] to the Act,

(g) "prescription" means an order given by a practitioner directing that a stated amount of any drug or mixture of drugs specified therein be dispensed for the person named in the order,

(h) "proper name" means, with reference to a drug, the name in English or French

(i) assigned to the drug in C.01.002,

(ii) that appears in bold-face type for the drug in these regulations,

(iii) specified in the Canadian licence in the case of drugs included in SCHEDULE C[1] or SCHEDULE D[2] to the Act, or

(iv) assigned in any of the publications mentioned in SCHEDULE B[1] to the Act in the case of drugs not included in (i), (ii), or (iii) of this paragraph,

(i) "proper name" means

(i) with reference to a vitamin mentioned in subparagraphs (i) to (xvii) of paragraph *(j)*, the name used for the vitamin in any of those subparagraphs, and

(ii) with reference to a vitamin mentioned in subparagraph (xviii) of paragraph *(j)*, the proper name of the vitamin from which the salt or derivative is obtained, and

(j) "vitamin" means

(i) **Vitamin A**,
(ii) **Provitamin A**,
(iii) **Thiamine**, **Thiamine Hydrochloride**, or **Vitamin B_1**,
(iv) **Riboflavin**,
(v) **Niacin**,
(vi) **Niacinamide**,
(vii) **Pyridoxine**, **Pyridoxine Hydrochloride**, or **Vitamin B_6**,
(viii) ***d*-Pantothenic Acid** or **Calcium *d*-Pantothenate**,
(ix) ***d*-Panthenol** or ***d*-Pantothenyl Alcohol**,
(x) **Folic Acid**,
(xi) **Biotin**,
(xii) **Vitamin B_{12}** or **Cyanocobalamin**,
(xiii) **Vitamin B Complex**,
(xiv) **Ascorbic Acid** or **Vitamin C**,
(xv) **Vitamin D**,
(xvi) **Vitamin E** or ***dl*, alpha-tocopheryl acetate**,
(xvii) **Vitamin K** or **Menadione**, and
(xviii) any salt or derivative of any vitamin mentioned in subparagraphs (i) to (xvii).

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[1] See page 9.
[2] See page 10.

D.01.002. This **Part** does not apply to a drug represented as containing a vitamin sold solely for veterinary use.[1]

D.01.003. Vitamin B_{12} for parenteral use[2] shall be of a potency of not less than 90 per cent of the amount of anhydrous vitamin B_{12} declared on the label.

D.01.004. Where a drug represented as containing a vitamin is put up in individual dosage or dispensing form or in ampoules or vials not prepared ready for injection, the amount of each vitamin contained therein

(a) in any individual dosage or dispensing form or in any ampoule or vial shall be not less than 90 per cent of the amount declared on the label,[3] and

(b) on the average shall be at least as great as the amount declared on the label[3], as determined by the official method.[4]

D.01.005. Subject to D.01.006, where the contents of a package of a food or drug represented as containing a vitamin are expressed in terms of weight, measure, or number, no variations from the quantity declared on the label[3] are permitted other than the following

(a) variations due exclusively to weighing, measuring, or counting that occur in packaging conducted in accordance with good commercial practice, which variations are, except for those drugs where the contents are expressed in terms of number, not to be such that the average content is less than the quantity declared on the label[3] as determined by the official method,[4]

(b) variations due exclusively to differences in the capacity of containers resulting solely from unavoidable difficulties in manufacturing, but no greater variation is permitted because of the design of the containers than is permitted in the case of containers of similar capacity that can be manufactured so as to be of approximately uniform capacity, and

(c) variations in weight or measure that unavoidably result from the ordinary and customary exposure of the package to evaporation or to the absorption of water under normal atmospheric conditions.

D.01.006. Notwithstanding D.01.005, where the contents of a package of a food or drug represented as containing a vitamin are expressed in terms of minimum weight, measure, or number, the contents of the package shall not be less than the minimum expressed.

D.01.007. Where a drug represented as containing a vitamin is put up in ampoules ready for parenteral use,[2] each ampoule of the drug shall contain an excess volume sufficient to permit the withdrawal of the volume declared on the label[3].

D.01.008. Where a drug represented as containing a vitamin is prepared for parenteral use[5] and contains a preservative ingredient, such ingredient

(a) shall be added only in an amount that is non-toxic and harmless in the dosage in which the drug is recommended to be used, and

(b) shall not interfere with the therapeutic properties of the drug.

D.01.009. No person shall sell[5] a drug represented as containing a vitamin that is prepared for parenteral use[2] unless the drug in its final container is tested by an acceptable method,[6] where such a test can be carried out, for identity, the presence of pyrogens, sterility and safety, and when so tested is found to be true to name, free of pyrogen, sterile and safe when used according to directions.

D.01.010. The immediate container of a drug represented as containing a vitamin that is prepared for parenteral use[2] shall be of such material and construction that

(a) no deleterious substance is yielded to the contents thereof, and

(b) if made of glass, it permits inspection of the contents.

D.01.011. Where a claim is made as to the vitamin potency of a food or drug, the food or drug shall have that vitamin potency as determined by an acceptable method.[6]

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[1] See C.01.604.
[2] See D.01.001 (*d*).
[3] See page 1, A.01.010 (*e*) (*i*), D.02.003.
[4] See A.01.010 (*h*).
[5] See page 1.
[6] See A.01.010 (*a*).

D.01.012. Except as provided in D.01.013, no person shall sell[1] a food or drug, represented as containing a vitamin in the form of a tablet which is intended to be swallowed whole, unless the tablet disintegrates in not more than 60 minutes when tested by the official method.[2]

D.01.013. The provisions of D.01.012 do not apply to tablets which are represented on the label[3] as being enteric coated, or as having delayed action.

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[1] See page 1.
[2] See A.01.010 (*h*).
[3] See page 1, A.01.010 (*e*) (*i*), D.02.003.

Labelling and Advertising

D.02.001. No person shall sell a food or a drug represented as containing a vitamin that is not labelled.[1]

D.02.002. Any statement or information required by these regulations to be carried on a label shall be legibly and conspicuously displayed thereon.

D.02.003. Where a package of a food or a drug represented as containing a vitamin has only one label,[1] that label shall contain all the information required by these regulations to be shown on both the inner and the outer labels.

D.02.004. No reference, direct or indirect, to the Act or to these regulations shall be made upon any label[1] of, or in any advertisement for a food or a drug represented as containing a vitamin unless such reference is a specific requirement of the Act or these regulations.

D.02.005. An advertisement to the general public or a label[1] shall not

(a) give assurances regarding results to be obtained from treatment by vitamin medication or from the addition of vitamins to the diet, or

(b) refer to, reproduce or quote any testimonial in specific cases regarding the action of any vitamin in a food or drug represented as containing the vitamin.

D.02.006. On any label[1] of or in any advertisement to the general public for a food or drug represented as containing a vitamin, the proper name[2] of the vitamin shall be displayed as conspicuously as any other name used therein for the vitamin.

D.02.007. Except as provided in these regulations, the label[1] of a package of food represented as containing a vitamin shall carry

(a) on the main panel of the label[1]

(i) the common name[3] of the food,

(ii) a declaration by name of any Class II, Class III, and Class IV preservative therein,

(iii) a declaration of any food colour[4] added thereto, and

(iv) a declaration of any artificial or imitation flavouring preparation added thereto,

(b) on the label[1]

(i) the name and address of the manufacturer of the food,

(ii) in the case of a food consisting of more than one ingredient and for which no standard is prescribed in these regulations for the food, a complete list of the ingredients by their common names in descending order of their proportions unless the quantity of each ingredient is stated in terms of percentage or proportionate composition,

(iii) except in the case of a food, the weight of which including the package in which it is contained is under two ounces, a correct statement of the net content in terms of weight, measure, or number in compliance with good commercial practice.

D.02.008. The label[1] of a food represented as containing a vitamin to which no vitamin has been added shall not, except in cases permitted by D.02.014, D.03.001 and D.03.002, carry any statement regarding the vitamin content of the food.

D.02.009. Where, in accordance with D.03.001, the label[1] of a food declares that the food is "an excellent dietary source" of a vitamin named on the label, no claim shall be made on the label of or in any advertisement for the action of that vitamin other than the general claims permitted by D.03.008, unless the amount of the vitamin contained in the food is more than the minimal amounts listed in D.03.004 *(a)* to *(k)* when the specific claims permitted by D.03.009 may be made.

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[1] See page 1, A.01.010 (*e*) (*i*), D.02.003.
[2] See D.01.001 (*i*).
[3] See D.01.001 (*a*).
[4] See B.06.

D.02.010. No claims shall be made on any label[1] of or in any advertisement for the action of a vitamin contained in a food that is labelled "a good dietary source" of a named vitamin as permitted by D.03.002.

D.02.011. No label[1] of or advertisement for a food shall mention pyridoxine, *d*-pantothenic acid, *d*-panthenol, folic acid, biotin, vitamin B_{12}, vitamin E or vitamin K.

D.02.012. Subject to D.02.013 and D.02.014, the label[1] of a food represented as containing a vitamin to which has been added a vitamin shall carry a statement of the amount of vitamin present in the food, expressed in terms of the proper name[2] of the vitamin only, in

(a) International Units per 100 grams or per 100 millilitres for vitamin A, provitamin A, vitamin D, and

(b) milligrams per 100 grams or per 100 millilitres for thiamine, riboflavin, niacin, niacinamide, and ascorbic acid.

D.02.013. Where a vitamin has been added to a food that is packaged in unit containers containing less than 100 grams or 100 millilitres, the label[1] of the food shall carry a statement of the amount of vitamin present therein expressed in terms of the proper name[2] only of the vitamin in

(a) International Units per package for vitamin A, provitamin A and vitamin D, and

(b) milligrams per package for thiamine, riboflavin, niacin, niacinamide, and ascorbic acid.

D.02.014. A food represented as containing a vitamin and that is used solely for feeding children under two years of age may carry a statement on the label[1] of its vitamin content in terms of the specified units per ounce.

D.02.015. The main panel of both the inner and the outer labels[1] of a drug represented as containing a vitamin shall carry

(a) the proper name and the standard under which the drug was manufactured which shall, if the standard is contained in any publication mentioned in SCHEDULE B to the Act, be stated in full or by the abbreviation therein provided, or if the standard is provided by DIVISION 5 or DIVISION 6 of **Part C** of these regulations, the standard shall be designated as Canadian Standard Drug or C.S.D. or, if the drug is manufactured under Canadian licence it shall be sufficient to state the Canadian licence number, and where there is a proprietary or brand name, the proper name shall immediately precede or follow the said proprietary or brand name in type of not less than one-half the size thereof, or

(b) if there is no proper name, the common name.

D.02.016. Both the inner and the outer labels[1] of a drug represented as containing a vitamin shall carry

(a) the name of the manufacturer[3] or distributor of the drug,

(b) the address of the manufacturer[3] or distributor, except that where the immediate container contains 5 millilitres or less, this statement need not be made on the inner label,

(c) where a drug is intended for internal[4] or parenteral[5] use, the lot number[6] thereof,

(d) adequate directions for use,

(e) the proper[2] or if there is no proper name the common name[7] of each medicinal ingredient contained therein except upon

(i) shipping cases or wrapping material,

(ii) official drugs,[8]

(iii) drugs sold on prescription,[9] or

(iv) medicines registered under the Proprietary or Patent Medicine Act, and

(f) a statement of the amount of each vitamin present in the drug, expressed in terms of the proper name[2] only of the vitamin in

(i) International Units per gram or per millilitre for vitamin A, provitamin A, vitamin D, and vitamin E,

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[1] See page 1, A.01.010 (*e*) (*i*), D.02.003.
[2] See D.01.001 (*i*).
[3] See A.01.010 (*g*).
[4] See C.01.001 (*d*).
[5] See C.01.001 (*g*).
[6] See A.01.010 (*f*).
[7] See C.01.001 (*b*).
[8] See D.01.001 (*c*).
[9] See D.01.001 (*g*).

(ii) milligrams per gram in the case of solids or viscous liquids, or per millilitre in the case of other liquids, for thiamine, riboflavin, niacin, niacinamide, pyridoxine, *d*-pantothenic acid, *d*-panthenol, folic acid, ascorbic acid, and vitamin K,

(iii) micrograms per gram in the case of solids or viscous liquids, or per millilitre in the case of other liquids, for biotin, and vitamin B_{12},

(iv) Oral Units for vitamin B_{12} with intrinsic factor concentrate, or

(v) for vitamin products put up in individual dosage or dispensing form, the specified units per individual dosage or dispensing form, and

(g) in the case of a complex salt or derivative of a vitamin, the name of the salt or derivative.

D.02.017. The outer label[1] of a drug represented as containing a vitamin shall carry

(a) a correct statement of net contents in terms of weight, measure, or number, and

(b) where the drug is intended for parenteral use,[2] the name and proportion of any preservative present therein.

D.02.018. Where any label[1] of a food or drug carries, in addition to the statements required by D.02.012, D.02.013, and D.02.016, a statement of the vitamin content of the product expressed in any other measure than those required by those sections, no such additional statement shall be more prominent than the statement required by those sections.

D.02.019. The inner and outer labels[1] of a food or drug represented as containing provitamin A shall describe the nature of the provitamin A.

D.02.020. The inner and outer labels[1] of a food or drug represented as containing a mixture of vitamin A and provitamin A shall show the proportions of each.

D.02.021. The inner and outer labels[1] of a food or drug represented as containing vitamin B complex shall carry a statement of the source of the vitamin B complex and the amount present per gram, per millilitre, or per individual dosage form, as the case may be, in the following manner: "Vitamin B Complex as derived from (naming the number) grams of (naming the source)".

D.02.022. Both the inner and the outer labels[1] of a drug represented as containing vitamin E shall carry a statement of the source and form of the active material.

D.02.023. Both the inner and the outer labels[1] of a drug represented as containing vitamin B_{12} shall carry a statement of the form of the vitamin B_{12} and the potency in terms of micrograms of vitamin B_{12} or cyanocobalamin.

D.02.024. Both the inner and the outer labels[1] of a drug represented as containing vitamin E, *d*-pantothenic acid *d*-panthenol or biotin other than

(a) a drug put up in ampoules for parenteral use, or

(b) a drug containing in the daily dose recommended on the label more than 25 International Units of vitamin E,

shall carry a statement that the significance of these vitamins in human nutrition has not been established.

D.02.025. No claim shall be made in an advertisement to the general public or on a label respecting the action of pyridoxine, *d*-pantothenic acid, *d*-panthenol, folic acid, biotin, vitamin B_{12} vitamin E, or vitamin K.

D.02.026. The inner and outer labels[1] of cod liver oil shall carry

(a) a statement of the vitamin A and the vitamin D content described in International Units per gram, except where it is put up in individual dosage or dispensing form when it shall be described in International Units per individual dosage or dispensing form,

(b) the recommended daily dosage, the content of which shall not exceed 10,000 International Units of vitamin A, and 2,000 International Units of vitamin D.

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[1] See page 1, A.01.010 (*e*) (*ii*), D.02.003.
[2] See D.01.001 (*c*).

D.02.027. The inner and outer labels[1] of an extract of cod liver, an extract of cod liver oil, an emulsion of cod liver oil, or a preparation purporting to contain these substances when intended for oral use shall carry

(a) a statement of the vitamin A and the vitamin D content in International Units per gram in the case of viscous liquids, or per millilitre in the case of other liquids, and recommended daily dose, the smallest of which shall contain not less than 1,600 International Units of vitamin A and 400 International Units of vitamin D, or

(b) a statement that the product is not a substitute for the vitamin activity of cod liver oil.

D.02.028. Both the inner and the outer labels[1] of halibut liver oil shall carry

(a) a statement of the vitamin A content in International Units per gram, except where it is put up in individual dosage or dispensing form when it shall be described in International Units per individual dosage or dispensing form,

(b) the recommended daily dosage, which shall not exceed 0·16 millilitre or 10,000 International Units of vitamin A, except where the label[1] carries the statement: "NOTE: For Therapeutic Use Only" and the product is not advertised to the general public.

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[1] See page 1, A.01.010 (*e*) (*i*), D.02.003.

Limits of Vitamin Content, Claims

D.03.001. No person shall claim that a food to which no vitamin has been added is "an excellent dietary source" of any vitamin named on the label[1] unless the food contributes in a reasonable daily intake, as ordinarily consumed or prepared as directed on the label,[1] not less of the vitamin in respect of which the claim is made than the amount listed herein for the vitamin

(a) for vitamin A, 1,200 International Units,

(b) for thiamine, 0·45 milligram,

(c) for riboflavin, 0·75 milligram,

(d) for niacin, 4·5 milligrams,

(e) for ascorbic acid, 15 milligrams,

(f) for vitamin D, 400 International Units,

(g) for vitamin B complex, an amount that will supply not less than the following amounts of any three of the following factors:

(i) 0·3 milligram of thiamine,
(ii) 0·3 milligram of riboflavin,
(iii) 1·5 milligrams of niacin,
(iv) 0·25 milligram of pyridoxine, or
(v) 0·5 milligram of *d*-pantothenic acid.

D.03.002. No person shall claim that a food to which no vitamin has been added is "a good dietary source" of any vitamin named on the label[1] unless the food contributes in a reasonable daily intake, as ordinarily consumed or prepared as directed on the label,[1] not less of the vitamin in respect of which the claim is made than the amount listed herein for the vitamin

(a) for vitamin A, 600 International Units,

(b) for thiamine, 0·25 milligram,

(c) for riboflavin, 0·4 milligram,

(d) for niacin, 2·5 milligrams,

(e) for ascorbic acid, 7·5 milligrams,

(f) for vitamin B complex, an amount that will supply not less than the following amounts of any three of the following:

(i) 0·15 milligram of thiamine,
(ii) 0·15 milligram of riboflavin,
(iii) 0·8 milligram of niacin,
(iv) 0·15 milligram of pyridoxine, or
(v) 0·25 milligram of *d*-pantothenic acid.

D.03.003. No person shall add a vitamin to a food in an amount that will, in a reasonable daily intake, contribute more than

(a) 2,500 International Units of vitamin A,

(b) 2 milligrams of thiamine,

(c) 3 milligrams of riboflavin,

(d) 20 milligrams of niacin or niacinamide,

(e) 60 milligrams of ascorbic acid, or

(f) 800 International Units of vitamin D.

D.03.004. No person shall sell[2] a food or drug represented as containing a vitamin, except those defined in D.03.001, D.03.002, and D.03.005, unless such food or drug contributes in the smallest recommended daily intake, where dosage is given, or otherwise in a reasonable daily intake, not less of the vitamin in respect of which the claim is made than the amount listed herein for the vitamin

(a) for vitamin A or provitamin A, 1,600 International Units,

(b) for thiamine, 0·6 milligram,

[1] See page 1, A.01.010 (*e*) (*i*), D.02.003.
[2] See page 1.

(c) for riboflavin, 1·0 milligram,

(d) for niacin or niacinamide, 6 milligrams,

(e) for pyridoxine, 1 milligram,

(f) for *d*-pantothenic acid or *d*-panthenol, 5 milligrams,

(g) for folic acid, 0·25 milligrams,

(h) for vitamin B_{12}, 2 micrograms,

(i) for ascorbic acid, 20 milligrams,

(j) for vitamin D, 400 International Units,

(k) for vitamin E, 10 International Units, or

(l) for vitamin B complex, an amount, obtained from a natural source, that is found in at least 5 grams of yeast or in an equivalent amount of yeast extract and that will supply not less than the following amounts of any three of the following factors:

(i) 0·4 milligram of riboflavin,

(ii) 2 milligrams of niacin,

(iii) 0·3 milligram of pyridoxine, or

(iv) 0·6 milligram of *d*-pantothenic acid.

D.03.005. No person shall sell[1] for use by children under six years of age a food or drug represented as containing a vitamin, except those defined in D.03.001 and D.03.002, unless such food or drug contributes in the smallest recommended daily intake, where dosage is given, or otherwise in a reasonable daily intake, not less of the vitamin in respect of which the claim is made than the amount listed herein for the vitamin

(a) for vitamin A or provitamin A, 1,000 International Units,

(b) for thiamine, 0·4 milligram,

(c) for riboflavin, 0·6 milligram,

(d) for niacin or niacinamide, 4 milligrams,

(e) for pyridoxine, 0·6 milligram,

(f) for *d*-pantothenic acid or *d*-panthenol, 3 milligrams,

(g) for folic acid, 0·25 milligrams,

(h) for vitamin B_{12}, 2 micrograms,

(i) for ascorbic acid, 20 milligrams,

(j) for vitamin D, 400 International Units.

D.03.006. No person shall

(a) sell[1] a drug represented as containing a vitamin that furnishes in the largest recommended daily intake, more than

(i) 10,000 International Units of vitamin A or provitamin A,

(ii) 4·5 milligrams of thiamine,

(iii) 7·5 milligrams of riboflavin,

(iv) 45 milligrams of niacin or niacinamide,

(v) 1 milligram of folic acid,

(vi) 14 micrograms of vitamin B_{12},

(vii) 150 milligrams of ascorbic acid,

(viii) 2,000 International Units of vitamin D,

(ix) 25 International Units of vitamin E, or

(x) any amount of vitamin K,

unless, subject to D.03.007, both the inner and the outer labels[2] carry the statement "NOTE: For Therapeutic Use Only", or

(b) advertise a drug specified in subsection *(a)* to the general public.

D.03.007. Notwithstanding D.03.006, the statement "NOTE: For Therapeutic Use Only" is not required

(a) on the inner label[2] of a drug represented as containing a vitamin put up in ampoules for parenteral use,[3] or

(b) on the inner and outer labels,[1] of drugs listed in SCHEDULE F[4] to the Act.

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[1] See page 1.
[2] See page 1, A.01.010 (*e*) (*i*), D.02.003.
[3] See D.01.001 (*c*).
[4] See page 10.

D.03.008. No person shall make any general claims to the general public based upon the vitamin content of a food or drug other than within the following limitations, namely, that vitamins

(a) are necessary for the normal functioning of the body,

(b) aid in growth,

(c) may help to maintain appetite, and

(d) may help to maintain normal resistance of the body to infection.

D.03.009. No person shall make any specific claims to the general public based upon the vitamin content of a food or drug other than within the following limitations, namely,

(a) for vitamin A or provitamin A, that this vitamin is essential for the maintenance of a healthy condition of the epithelium, that it is specific in the prevention and treatment of nutritional night blindness or nyctalopia of dietary origin, and that it prevents, or relieves, if not too far advanced, xerophthalmia due to vitamin A deficiency,

(b) for thiamine, that this vitamin prevents or alleviates beriberi, that it protects against and aids in the treatment of neuritis due to thiamine deficiency, and that the need of the organism for thiamine is increased when metabolism is greatly augmented as it may be in pregnancy, fever, hyperthyroidism, and infectious diseases,

(c) for riboflavin, that this vitamin is specific in the prevention and treatment of ariboflavinosis of dietary origin,

(d) for niacin or niacinamide, that this vitamin is of value in the prevention and treatment of pellagra,

(e) for vitamin B complex, that the combined action of the factors of the vitamin B complex aids in the utilization of foodstuffs,

(f) for ascorbic acid, that this vitamin is specific in the prevention and treatment of scurvy, that it is a factor in the normal development and maintenance of bones, cartilages, teeth and gums, and that the need of the organism for ascorbic acid is increased in fever,

(g) for vitamin D, that this vitamin is essential in the prevention of rickets and in the normal development of bones and teeth, and that the requirement for vitamin D is greatest in infancy and childhood, and during pregnancy and lactation.

COSMETICS

E.01.001. No person shall sell[1] a cosmetic that is not labelled as required by these regulations.

E.01.002. Except as provided in this **Part** a cosmetic shall carry

(a) on both the inner and the outer labels[2]

(i) the name, if any, of the cosmetic, and the description of the cosmetic if necessary for the identification thereof, and

(ii) the name and address of the manufacturer[3] or distributor, and where a manufacturer or distributor has more than one place of business such address shall be that of his head office or principal place of business, but the address of any branch place of business may be printed on the label in type no larger than that used for printing the address of the head office or principal place of business,

(b) on the outer label,[2] a declaration of the net content expressed in terms of

(i) weight for solids,

(ii) fluid measure for liquids, or

(iii) weight for semi-solids except that fluid measure may be used if in accordance with established commercial practice and it gives accurate information in respect of the net content,

combined with numerical count if the content is subdivided, and

(c) on the inner label[2]

(i) where a hazard exists adequate directions for safe use, and

(ii) any warning, caution or special direction required by these regulations to be placed thereon.

E.01.003. Notwithstanding E.01.002, a statement of the content need not appear on the outer label[2] of

(a) a package of perfume, toilet water or the like the net content of which does not exceed 4 fluid ounces, and

(b) a package of solid or liquid cosmetic the net content of which does not exceed one ounce.

E.01.004. No manufacturer[3] shall, on any label[2] of, or in any advertisement for a cosmetic, make any claim respecting the action or effect of the cosmetic or any ingredient therein in cleansing, improving or altering the complexion, skin, hair or teeth, unless such claim

(a) has general recognition as being proper, or

(b) is supported by adequate and proper tests, and he maintains satisfactory records of such tests, and supplies the Director with copies of such records upon request.

E.01.005. Any statement or information required by this **Part** to appear on a label[2] shall be legibly and conspicuously displayed thereon.

E.01.006. Where a package of a cosmetic has only one label,[2] such label shall contain all the information required by these regulations to be shown on both the inner and the outer labels.

E.01.007. No reference direct or indirect to the Act or to these regulations shall be made upon any label of or in any advertisement for a cosmetic unless such reference is a specific requirement of the Act or of these regulations.

E.01.008. No person shall sell[1] a cosmetic in the manufacture of which a coal tar colour is used that contains more than

(a) 1·4 parts per million of arsenic calculated as arsenic,

---

[1] See page 1.
[2] See page 1, A.01.010 (*e*) (*f*), E.01.006.
[3] See A.01.010 (*g*).

(b) 20 parts per million of lead calculated as lead,

(c) 100 parts per million of heavy metals other than lead calculated as the total of the respective metals.

E.01.009. Upon written request of the Director, a manufacturer[1] of any cosmetic shall furnish adequate samples of any coal tar colour used by him.

E.01.010. No person shall sell[2] any eyebrow or eyelash colour that contains any coal tar dye, coal tar dye base, or coal tar dye intermediate.

E.01.011. No person shall sell[2] any hair dye that contains paraphenylenediamine, or other coal tar dye base or coal tar dye intermediate, unless the following legend appears, upon both the inner and the outer labels:[3]

> "CAUTION:—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness",

and instructions for carrying out the test as follows, or in words of like import, shall accompany each immediate package:

> This preparation may cause serious inflammation of the skin in some persons and a preliminary test should always be carried out to determine whether or not special sensitivity exists. To make the test, cleanse a small area of skin behind the ear or upon the inner surface of the forearm, using either soap and water or alcohol. Apply a small quantity of the hair dye as prepared for use to the area and allow to dry. After twenty-four hours wash the area gently with soap and water. If no irritation or inflammation is apparent, it is usually assumed that no hypersensitivity to the dye exists. The test should, however, be carried out before each and every application. Do not on any account use for dyeing eyebrows or eyelashes as severe inflammation of the eye or even blindness may result.

E.01.012. No person shall sell[2] any cosmetic which carries on the label[3] thereof or in any advertisement therefor, any symbol or device to denote that the cosmetic has been prepared or compounded in accordance with a prescription.

E.01.013. A manufacturer who in the course of compounding, finishing or packaging a cosmetic changes the composition of material imported from a country, district or other place of origin outside Canada other than by a simple dilution with a solvent, shall not, in naming or describing the cosmetic, employ in any form the name of such country, district or other place of origin, but may make a simple statement of fact regarding the nature and source of any of the ingredients used therein, including the extent of the operations carried out by him.

E.01.014. Notwithstanding the provision of C.02.005 no person shall sell[2] a preparation manufactured for use as a cosmetic containing a sex hormone represented as having oestrogenic properties unless the cosmetic is demonstrated to be free from systemic effect from sex hormones, and the label[3] bears

(a) on both the inner and the outer labels[3]

(i) the name and address of the manufacturer[1] or distributor,

(ii) the name of the preparation,

(iii) a declaration of the sex hormones present by their proper names,

(iv) the sex hormone potency as defined in C.02.002, and

(v) the statement "Use only as directed", and

(b) on the outer label[3]

(i) a statement of net content as required by E.01.002 *(b)*, and

(ii) directions for use.

---

[1] See A.01.010 (*g*).
[2] See page 1.
[3] See page 1, A.01.010 (*s*) (*i*), E.01.006.

E.01.015. No person shall sell[1] a cosmetic in a collapsible tube packed in a carton if the dimensions of the carton exceed

(a) for all tubes without chip-board protectors, and tubes of less than 1 1/4″ diameter with chip-board protectors:—

(i) length—over-all tube length filled and clipped plus 8/32″,

(ii) height—diameter of tube plus 4/32″,

(iii) width—1·25 times tube diameter plus 4/32″, and

(b) for all tubes of 1 1/4″ diameter and over with chip-board protectors:—

(i) length—over-all tube length filled and clipped plus 10/32″,

(ii) height—diameter of tube plus 4/32″, and

(iii) width—1·25 times tube diameter plus 4/32″.

E.01.016. Notwithstanding E.01.015, when an applicator is essential to the use of a cosmetic sold in a collapsible tube packed in a carton, and such applicator is included in the carton, the dimensions of the carton may exceed those set out in E.01.015 provided that the main panel of the label of the carton clearly indicates that it is a combination package.

E.01.017. No person shall sell[1] a cosmetic that is recommended for removing stains from the teeth that has an acidity greater than that represented by a pH of 4.

[1] See page 1.

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139, December 28, 1956.
Replaces page 139, September 6, 1956.

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L. E. Thompson
E. B. Thurlow
H. W. Wagner

140, December 28, 1956.
Replaces page 140, September 20, 1956.

FORMS

DEPARTMENT of NATIONAL HEALTH and WELFARE

This is to certify that

Mr.....pursuant to Order in Council P.C.....of the.....day of.....19.... has been designated by the Governor in Council as an Inspector under the Food and Drugs Act.

.....	.....
Bearer	Deputy Minister, National Health.

NEW ☐

RENEWAL ☐

CANADA

APPLICATION FOR A LICENCE TO MANUFACTURE DRUGS MENTIONED OR DESCRIBED IN SCHEDULES C AND D TO THE FOOD AND DRUGS ACT.

To the Deputy Minister of National Health
and Welfare, Ottawa, Canada.

I,
We, _____

of _____

hereby apply for a licence (*) to manufacture at _____
the undermentioned products for sale:—

Proper Name	Trade Name

* 1. Applicants should note carefully the requirements of Part C, Divisions 3 and 4 of the Food and Drug Regulations when completing this application.
2. Applicants should specify in connection with each product covered by this application, whether or not the product is wholly manufactured within their own establishment, and if not, a report should form part of this application which will disclose what part of the processing is carried out by each manufacturer participating in the manufacture of the product.
3. Applicants not resident in Canada must indicate the name and address of their Canadian distributor, if any, in this application.

and { I / We } undertake to comply with all requirements of the Food and Drugs Act, Chap. 38 S.C., 1953 and the regulations made thereunder.

The names and qualifications of the expert staff responsible for the manufacture or testing of the above-mentioned products are as follows:—

Names	Academic Degrees and Qualifications

Date_____

Signature_____

Western Region

Room 504, Federal Building,
325 Granville Street,
VANCOUVER, B.C.

Superintendent of Inspection Services ..... E. L. Devlin

Food and Drug Inspector ..... L. Devlin
Food and Drug Inspector ..... F. R. Holding
Food and Drug Inspector ..... M. W. MacDonald
Food and Drug Inspector ..... A. J. Sandbrook
Food and Drug Inspector ..... L. E. Thompson

Room 408,
Belmont Building,
805 Government Street,
VICTORIA, B.C.

Food and Drug Inspector ..... E. T. Ketcheson

Room 7,
345 Victoria Street,
KAMLOOPS, B.C.

Food and Drug Inspector ..... J. A. Hunter

404 Post Office Building,
EDMONTON, Alta.

Food and Drug Inspector ..... H. W. Wagner

Customs Building,
CALGARY, Alta.

Food and Drug Inspector ..... A. J. Beaton

West Central Region

Aragon Building,
244 Smith Street,
WINNIPEG, Man.

Superintendent of Inspection Services ..... F. A. Kirby

Food and Drug Inspector ..... R. J. Baker
Food and Drug Inspector ..... W. F. Daniels
Food and Drug Inspector ..... L. E. Smith
Food and Drug Inspector ..... A. B. Tennenhouse

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REGINA, Sask.

Food and Drug Inspector ..... F. E. Moynihan

146, September 20, 1956.
Replaces page 146, May 30, 1956.

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SASKATOON, Sask.

Food and Drug Inspector ..... J. B. Ellingham

Room 313,
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PORT ARTHUR, Ontario.

Food and Drug Inspector ..... N. M. McMurchy

Central Region

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TORONTO, Ontario.

Superintendent of Inspection Services ..... D. A. Gray

Food and Drug Inspector ..... H. Bernholtz
Food and Drug Inspector ..... D. G. Burvill
Food and Drug Inspector ..... R. T. Ferrier
Food and Drug Inspector ..... G. A. Hart
Food and Drug Inspector ..... A. H. Higuchi
Food and Drug Inspector ..... M. F. Johnstone
Food and Drug Inspector ..... O. B. Petursson
Food and Drug Inspector ..... C. M. Phillips
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Food and Drug Inspector..... R. Dufault
Food and Drug Inspector..... G. R. Guerin
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Food and Drug Inspector..... B. M. Crowe
Food and Drug Inspector..... J. F. Harris

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P.O. Box 324,
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Food and Drug Inspector ..... G. E. MacDonald

250 Prince William Street,
SAINT JOHN, N.B.

Food and Drug Inspector ..... H. T. C. Hutton
Food and Drug Inspector ..... Y. J. Richard

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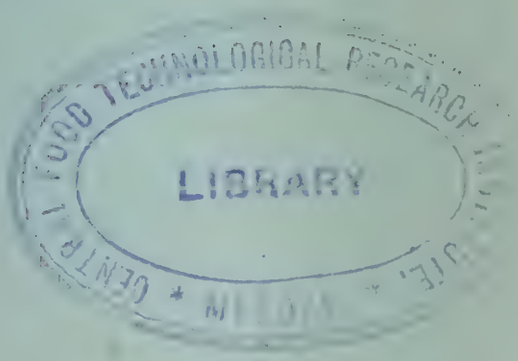

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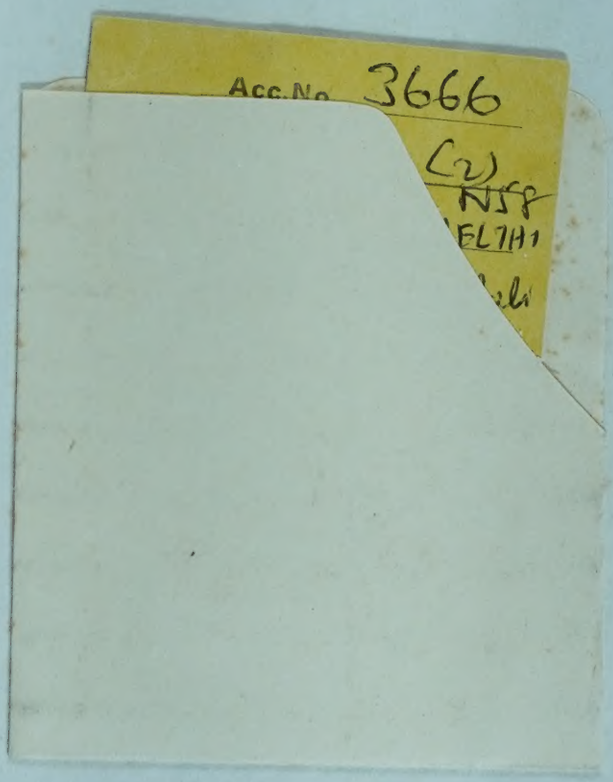
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